

Clinical Gastroenterology

# Pocket Handbook of GI Pharmaco- therapeutics

Edited by  
George Y. Wu  
and Achilles Pappano

 Humana Press

POCKET HANDBOOK OF  
GI PHARMACOTHERAPEUTICS

# CLINICAL GASTROENTEROLOGY

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*GEORGE Y. WU, SERIES EDITOR*

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POCKET HANDBOOK OF  
GI PHARMACOTHERAPEUTICS

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## PREFACE

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The number of agents for the treatment of digestive diseases and conditions has increased greatly, and in some cases, one is confronted with a bewildering array of brand and generic names. Although databases and reference books provide detailed information on pharmacology, toxicology, and therapeutics, obtaining commonly needed information, such as recommended first line agents, dosage, duration, side effects, and drug interactions, requires sifting through other materials. There is no text that contains just this practical pharmacological information. The purpose of this project is to remedy this deficiency with a small portable text.

Because treatment questions generally begin with diagnoses, each chapter addresses therapy of a digestive disease or condition, listed in the contents. Treatment algorithms are provided where available. Agents recommended for treatment of the condition are described in detail, including brand and generic names, indications, contraindications, side effects, drug interactions, doses/routes of administration, durations, and approximate costs. In addition, an index at the end of this handbook lists all the drugs in alphabetical order for those interested in specific agents.

Although the physical characteristics enhance its portability and convenience, as with other books in this series, we believe that the practical clinical information presented in this simple format will be of greatest value.

*George Y. Wu  
Achilles Pappano  
Farmington, Connecticut  
July 22, 2008*

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# CONTENTS

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Preface .....	v
<i>George Y. Wu, Achilles Pappano</i>	
Contributors .....	ix
<b>I Gastroesophageal Diseases</b>	
<b>1 Peptic Disorders</b> .....	3
<i>Lisa Rossi and Shishir Mathur</i>	
<b>2 Gastrointestinal Bleeding</b> .....	13
<i>Lisa Rossi and Shishir Mathur</i>	
<b>3 General GI Motility Disorders</b> .....	19
<i>Lisa Rossi</i>	
<b>4 Specific GI Motility Disorders</b> .....	31
<i>Lisa Rossi and Shishir Mathur</i>	
<b>5 Inflammatory Bowel Disease</b> .....	37
<i>Shilpa Madadi and Shishir Mathur</i>	
<b>6 General GI Infections</b> .....	49
<i>Marcy Coash and Shishir Mathur</i>	
<b>7 Specific GI Microbial Infections</b> .....	57
<i>Shilpa Madadi, Vivian Teixeira, and Shishir Mathur</i>	
<b>II Liver Disease</b>	
<b>8 Hepatitis</b> .....	85
<i>Shilpa Madadi and Shishir Mathur</i>	
<b>9 Cholestasis</b> .....	99
<i>Shishir Mathur</i>	
<b>10 Hepatic Encephalopathy</b> .....	101
<i>Shilpa Madadi and Shishir Mathur</i>	

---

<b>11 Pruritis</b> .....	105
<i>Marcy Coash</i>	
<b>12 Nutrition and Enzyme Deficiency</b> .....	107
<i>Shishir Mathur</i>	
References .....	113
Index .....	115



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# 1

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## Peptic Disorders

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*Lisa Rossi, MD*  
*and Shishir Mathur, MBBS*

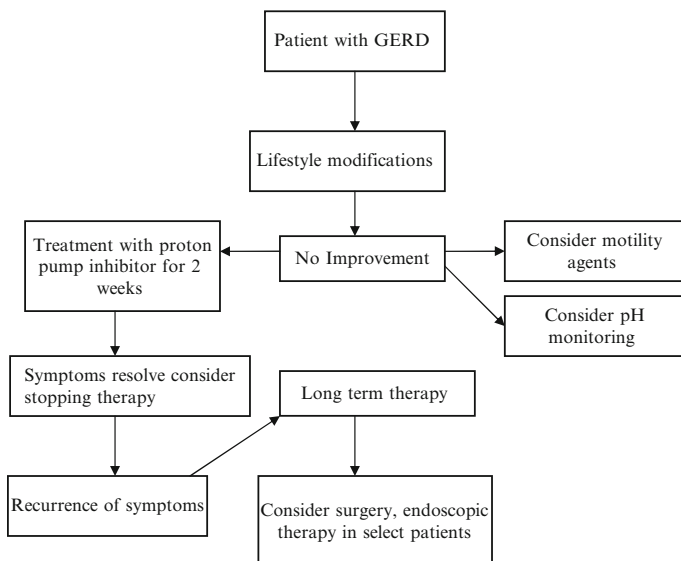
### CONTENTS

GASTROESOPHAGEAL REFLUX DISORDER (GERD)  
AND PEPTIC ULCER DISEASE (PUD)  
PROTON PUMP INHIBITORS  
HISTAMINE H<sub>2</sub> ANTAGONISTS  
OTHER AGENTS  
HELICOBACTER PYLORI

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## GASTROESOPHAGEAL REFLUX DISORDER (GERD) AND PEPTIC ULCER DISEASE (PUD)



## PROTON PUMP INHIBITORS

### *Omeprazole*

Trade name: Prilosec, Prilosec OTC

Manufacturer: AstraZeneca, Proctor and Gamble, generic

Dosage:

- GERD/erosive esophagitis: 20 mg p.o. q.d. for 4 weeks
- Gastric ulcer: 40 mg p.o. q.d. for up to 4–8 weeks
- Duodenal ulcer: 20–40 mg p.o. q.d. for 4–8 weeks
- *Helicobacter pylori* infection: 20 mg p.o. b.i.d. in conjunction with triple therapy
- Stress ulcer prophylaxis: 40 mg p.o. q.d. initially, then 20–40 mg daily
- Gastric hypersecretion: 60 mg p.o. q.d. initial dose, increase up to 120 mg p.o. t.i.d.

**Contraindications/cautions:**

- Hypersensitivity to omeprazole
- Caution in hypocalcemia, hypokalemia, metabolic alkalosis, respiratory alkalosis, Bartter's syndrome (powder for oral suspension contains 1,680 mg or 20 mEq of sodium bicarbonate)

**Adverse effects:**

- Gastrointestinal: Abdominal pain, diarrhea, pancreatitis, hepatotoxicity
- Neurologic: Headache
- Renal: Interstitial nephritis
- Musculoskeletal: Hip fracture, rhabdomyolysis

**Drug interactions:**

- Increases levels of warfarin, cyclosporine, digoxin, phenytoin
- Decreases levels of atazanavir, ketoconazole, itraconazole, cefuroxime

Pregnancy category: C

Lactation: Probably safe

Relative cost: (\$\$)

### ***Esomeprazole Magnesium (Oral)***

### ***Esomeprazole Sodium (IV)***

Brand name: Nexium

Manufacturer: AstraZeneca

**Dosages:**

- GERD/erosive esophagitis: 20–40 mg p.o. q.d. for treatment
- Maintenance therapy in GERD/erosive esophagitis: 20 mg p.o. q.d.
- Gastric ulcer: 20–40 mg p.o. q.d. for up to 6 months
- Acute non-variceal upper gastrointestinal (GI) bleed: 80 mg i.v. bolus followed by continuous infusion at 8 mg/h. for 72 h. after endoscopic therapy
- *H. pylori* infection: 40 mg p.o. q.d. in conjunction with triple therapy
- Zollinger-Ellison syndrome: 40 mg b.i.d. increase up to 240 mg per day based on symptoms

**Contraindications/cautions:**

- Hypersensitivity to esomeprazole or benzimidazoles
- Caution with liver disease

**Adverse effects:**

- Gastrointestinal: Abdominal pain, constipation, diarrhea, flatulence, nausea, pancreatitis (rare)
- Neurologic: Headache
- Dermatologic: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis
- Musculoskeletal: Hip fracture, rhabdomyolysis

Drug interactions: See omeprazole

Pregnancy category: B

Lactation: Probably safe

Relative cost: Oral – \$\$, i.v. – \$\$\$

### *Lansoprazole*

Brand name: Prevacid

Manufacturer: TAP Pharmaceuticals, Inc.

Dosage:

- Duodenal ulcer: 15 mg p.o. q.d. or b.i.d. for 4–8 weeks
- *H. pylori* treatment: 30 mg p.o. b.i.d. for 10–14 days in combination with triple therapy
- Erosive esophagitis: 30 mg p.o. q.d. or b.i.d. for 4–8 weeks
- Gastric ulcer prophylaxis with NSAID use: 15–30 mg p.o. q.d.
- Gastric ulcer treatment: 30 mg p.o. q.d. or b.i.d. for 8 weeks
- GERD: 15–30 mg p.o. q.d. for 8 weeks
- Zollinger-Ellison syndrome: 60 mg p.o. q.d. to 90 mg b.i.d.

Contraindications/cautions:

- Hypersensitivity of lansoprazole or any of its components
- Caution in phenylketonurics: Oral disintegrating tablets contain phenylalanine
- Caution in liver disease (dose reduction may be required)

Adverse effects:

- Gastrointestinal: Abdominal pain, diarrhea, nausea
- Neurologic: Headache
- Musculoskeletal: Hip fracture, rhabdomyolysis
- Other: Fatigue

Drug interactions: See omeprazole

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$\$

### *Pantoprazole Sodium Oral and IV*

Brand name: Protonix

Manufacturer: Wyeth-Ayerst

Dosage:

- Erosive esophagitis (short term): 40 mg p.o. q.d. for 8–16 weeks or 40 mg i.v. for 7–10 days
- Esophagitis maintenance (GERD): 40 mg p.o. q.d.

- Duodenal ulcer: 40–80 mg p.o. q.d. for 4–8 weeks
- Acute non-variceal upper GI bleed: 80 mg i.v. bolus followed by continuous infusion at 8 mg/h. for 72 h. after endoscopic therapy
- Gastric hypersecretion (long term): 40 mg p.o. b.i.d., can increase to a maximum of 240 mg q.d.
- Gastric hypersecretion associated with pathologic conditions: 40 mg p.o. b.i.d. or 80 mg i.v. b.i.d., can increase up to 240 mg/per day

Contraindications/cautions:

- Hypersensitivity to pantoprazole products
- Use with caution in Bartter's syndrome, hypocalcemia, hypokalemia, metabolic alkalosis (powder for oral suspension contains 1,680 mg (20 mEq of sodium bicarbonate).

Adverse effects:

- Gastrointestinal: Diarrhea, pancreatitis, hepatotoxicity
- Renal: Interstitial nephritis
- Endocrine: Hyperglycemia
- Immunologic: Stevens-Johnson syndrome
- Musculoskeletal: Hip fracture, rhabdomyolysis

Drug interactions: See omeprazole

Lactation: Probably safe

Pregnancy category: B

Relative cost: Oral – \$\$, i.v. – \$\$\$

### ***Rabeprazole Sodium***

Brand name: Aciphex

Manufacturer: Eisai

Dosage:

- Duodenal ulcer disease: 20 mg p.o. q.d. after the morning meal for up to 4 weeks
- Gastric hypersecretion: Initial, 60 mg p.o. q.d., may increase up to 120 mg; single daily doses up to 100 mg/day may be given; 120 mg dose may require divided doses, 60 mg b.i.d.
- Gastroesophageal reflux disease, erosive or ulcerative, maintenance: 20 mg p.o. q.d.
- Gastroesophageal reflux disease, erosive or ulcerative, treatment: 20 mg p.o. q.d. for 4–8 weeks
- Gastroesophageal reflux disease, symptom control: 20 mg p.o. q.d. for 4 weeks
- *H. pylori* treatment with triple therapy: 20 mg p.o. b.i.d. for 7 days

**Contraindications/cautions:**

- Hypersensitivity to rabeprazole/substituted benzimidazoles
- Caution in liver disease

**Adverse effects:**

- Neurologic: Headache
- Immunologic: Stevens-Johnson syndrome
- Musculoskeletal: Hip fracture, rhabdomyolysis

Drug interactions: See omeprazole

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$\$

## HISTAMINE H2 ANTAGONISTS

### *Famotidine*

Trade name: Pepcid, Pepcid AC

Manufacturer: Merck & Co., Inc.

**Dosage:**

- Duodenal ulcer disease: 40 mg p.o. q.h. or 20 mg p.o. b.i.d. or 20 mg i.v. q.12h.
- Duodenal ulcer disease (maintenance): 20 mg p.o. q.h.
- Esophagitis/GERD: 20–40 mg p.o. b.i.d. for 12 weeks, 20 mg i.v. q.12h.
- Gastric hypersecretion: 20 mg to 160 mg p.o. q.6h., 20 mg i.v. q.12h.
- Gastric ulcer: 40 mg p.o. q.h., 20 mg i.v. q.12h.
- GERD short-term symptom relief: 20 mg p.o. b.i.d. for 6 weeks, 20 mg i.v. q.12h.
- Indigestion: 10–20 mg p.o. b.i.d.

**Contraindications/cautions:**

- Hypersensitivity to Pepcid or any of its components
- History of hypersensitivity to other H2 receptor antagonists
- Dose adjustment by 50% or increase interval to 24–36 h. for CrCl < 50 ml/min

**Adverse effects:**

- Gastrointestinal: Constipation, diarrhea, necrotizing enterocolitis in fetus or newborn, increased liver enzymes
- Neurologic: Dizziness

**Drug interactions:**

- May decrease efficacy of oral iron preparations, antifungals, and atazanavir
- May increase levels of fluvastatin and increase risk of rhabdomyolysis

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$\$

## ***Ranitidine Hydrochloride***

Trade name: Zantac

Manufacturer: Boehringer Ingelheim Pharmaceuticals, Inc. (OTC) and GlaxoSmithKline (Rx)

Dosage:

- Duodenal ulcer: 150 mg p.o. b.i.d. or 300 mg q.d.
- Duodenal ulcer: 50 mg i.v. q.6–8h. or 6.25 mg/h. continuous infusion
- Duodenal ulcer (maintenance): 150 mg p.o. q.d.
- Erosive esophagitis: 150 mg p.o. q.i.d. initially, then 150 mg p.o. b.i.d.
- Gastric ulcer: 150 mg p.o. b.i.d.
- Gastric ulcer (maintenance): 150 mg p.o. q.d.
- GERD: 150 mg p.o. b.i.d.

Contraindications/cautions:

- Hypersensitivity to ranitidine or any of its components

Adverse effects:

- Gastrointestinal: Abdominal pain, constipation, diarrhea, nausea, vomiting, necrotizing enterocolitis in fetus or newborn, pancreatitis
- Neurologic: Dizziness, headache, insomnia, somnolence
- Cardiovascular: Bradyarrhythmia
- Psychiatric: Agitation
- Other: Fatigue

Drug interactions:

- May decrease efficacy of oral iron preparations, antifungals, and atazanavir
- May increase levels of fluvastatin and increase risk of rhabdomyolysis
- Tenofovir may increase ranitidine levels

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$

## **OTHER AGENTS**

### ***Carafate***

Trade name: Sulcralfate

Manufacturer: Axcan Pharma

Dosage:

- Duodenal ulcer disease, active: 1 g p.o. q.i.d. or 2 g b.i.d. for 4–8 weeks
- Duodenal ulcer disease, maintenance: 1 g p.o. b.i.d.
- Gastric ulcer, maintenance: 1 g p.o. b.i.d.
- Stress ulcer, prophylaxis: 1 g p.o. q.h.



Contraindications/cautions:

- Hypersensitivity to sucralfate products

Adverse effects:

- Gastrointestinal: Constipation, bezoar
- Other: Aluminum toxicity, renal impaired patients

Pregnancy category: B

Lactation: Safety unknown

Relative cost: \$

## HELICOBACTER PYLORI

Bismuth Triple Therapy

- Bismuth 2 tablets q.i.d., metronidazole 250 mg p.o. q.i.d., tetracycline 500 mg q.i.d.

PPI Triple Therapy

- PPI twice a day + two of the following: amoxicillin (1 g p.o. b.i.d.), clarithromycin (500 mg b.i.d.), metronidazole (500 mg b.i.d.)

Quadruple Therapy

- PPI + metronidazole (500 mg t.i.d.), tetracycline (500 mg t.i.d. or q.i.d. times daily), bismuth subsalicylate or subcitrate (t.i.d. or q.i.d. times daily).

### *Amoxicillin*

Trade names: Amoxicot, Amoxil, Amoxil Pediatric Drops, Biomox, Dispermox, Trimox, Wymox

Manufacturer: Generic; Amoxil – GlaxoSmithKline; Dispermox – Ranbaxy; Trimox – Apothecon, Inc.

Dosage: For *H. pylori* eradication – 1 g p.o. b.i.d. in combination with PPI and other antibiotics

Contraindications/cautions:

- Hypersensitivity to amoxicillin
- Infectious mononucleosis: Risk of developing skin rash
- Caution in phenylketonurics
- Hypersensitivity to cephalosporins: Risk of cross reactivity

Adverse effects:

- Gastrointestinal: Diarrhea, nausea, vomiting
- Immunologic: Immune hypersensitivity reaction
- Dermatologic: Rash

Drug interactions:

- Typhoid vaccine, live oral: Antibiotic may inactivate vaccine

Pregnancy category: B

Lactation: Safe

Relative cost: \$

### ***Clarithromycin***

Trade names: Biaxin, Biaxin Filmtab, Biazin XL

Manufacturer: Generic; Biaxin – Abbott Laboratories

Dosage:

- *H. pylori* eradication – 500 mg p.o. b.i.d. in combination with PPI and other antibiotics

Contraindications/cautions:

- Concomitant cisapride, pimozone, astemizole, terfenadine, ergotamine, or dihydroergotamine
- Hypersensitivity to clarithromycin, erythromycin, or any macrolide antibiotics
- Dose adjustment required in renal failure patients

Adverse effects:

- Gastrointestinal: Abdominal discomfort, abdominal pain, diarrhea, disorder of taste, indigestion, nausea, liver failure
- Neurologic: Headache
- Immunologic: Immune hypersensitivity reaction (severe), anaphylaxis, Stevens-Johnson syndrome, toxic epidermal necrolysis

Drug interactions:

- Phenothiazines, cisapride, dofetilide, pimozone, ranolazine: Increased risk of QT prolongation and cardiac arrhythmias
- Ergot alkaloids: Increased risk of ergot toxicity, severe vasospasm, and ischemia
- Eplerenone: Risk of hyperkalemia

Pregnancy category: C

Lactation: Safety unknown

Relative cost: \$\$

### ***Metronidazole***

Please see Chap. 6 for drug details.

# 2

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## Gastrointestinal Bleeding

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*Lisa Rossi, MD*  
*and Shishir Mathur, MBBS*

### *CONTENTS*

ACUTE NON-VARICEAL UPPER GASTROINTESTINAL  
BLEEDING  
ACUTE HEMORRHAGE FROM ESOPHAGEAL  
VARICES

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### ACUTE NON-VARICEAL UPPER GASTROINTESTINAL BLEEDING

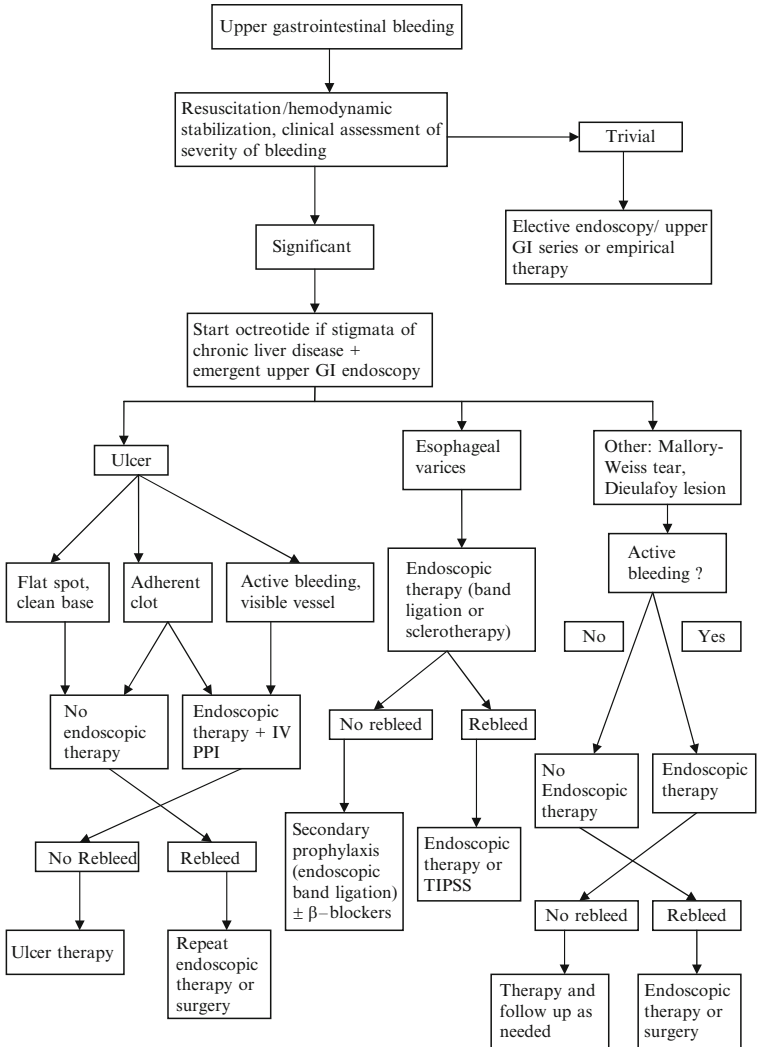
#### *Pantoprazole Sodium*

Acute non-variceal upper GI bleed: 80mg i.v. bolus followed by continuous infusion at 8 mg/h for 72h. after endoscopic therapy

#### *Esomeprazole*

Acute non-variceal upper GI bleed: 80mg i.v. bolus followed by continuous infusion at 8 mg/h. for 72h. after endoscopic therapy

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## ACUTE HEMORRHAGE FROM ESOPHAGEAL VARICES

### *Octreotide Acetate*

Trade name: Sandostatim

Manufacturer: Abraxis, Novartis

## Dosage:

- Acute variceal hemorrhage: 50–100 mcg i.v. bolus followed by 25–50 mcg/h. i.v. infusion
- Small intestinal bacterial overgrowth: 50 mg s.c. q.d. for 3 weeks
- VIPoma-associated diarrhea: 150–750 mcg s.c./i.v. divided in b.i.d.–q.i.d. dose for 2 weeks, then titrate for response
- Carcinoid tumor symptoms: 50–150 mcg s.c./i.v. b.i.d.–q.i.d. Maximum 1,500 mcg/day, titrate based on response for flushing and diarrhea
- Acute carcinoid crisis: 50–500 mcg i.v. p.r.n. or 50 mcg/h. i.v. infusion for 8–24h.
- Carcinoid crisis prophylaxis: 250–500 mcg i.v. x1. Information: Give 1–2 h preoperatively
- Secretory diarrhea: 50–500 mcg s.c./i.v. q.d.–t.i.d., titrate based on response
- Dumping syndrome: 50–100 mcg s.c. before meals

## Contraindications:

- Sensitivity to octreotide or any of its components

## Adverse effects:

- Gastrointestinal: Abdominal discomfort, constipation, diarrhea, flatulence, nausea, pancreatitis, cholelithiasis, ascending cholangitis, cholecystitis, cholestatic hepatitis
- Neurologic: Dizziness, headache
- Cardiovascular: Cardiac dysrhythmia, congestive heart failure (rare), sinus bradycardia
- Endocrine: Hyperglycemia, hypoglycemia, hypothyroidism

## Drug interactions:

- Contraindicated with cisapride and pimozide because of risk of QT prolongation
- Caution with calcium channel blockers because of risk of bradycardia and cardiac conduction abnormalities

Pregnancy category: B

Lactation safety: Unknown

Relative cost: \$\$\$\$

## *Vasopressin*

Tradename: Pitressin

Manufacturer: Parke-Davis

## Dosage:

- Variceal bleed 20 units i.v. over 20 min followed by 0.2–0.4 units/min; administer with nitroglycerin to control vasoconstrictive complications

- Abdominal distension; prophylaxis – Postoperative complication: initial, 5 units i.m. (0.25 mL) postoperatively; increase to 10 units (0.5 mL) at subsequent injections repeated at 3- or 4-h. intervals if necessary

Contraindications:

- Anaphylaxis or hypersensitivity to the drug or its components
- Chronic nephritis with nitrogen retention contraindicates the use of vasopressin until reasonable nitrogen blood levels have been attained
- Caution in patients with heart failure, coronary artery disease, epilepsy, and asthma

Adverse effects:

- Gastrointestinal: Nausea, flatus, abdominal cramps, vomiting
- Neurologic: Headache, tremor, vertigo
- Cardiovascular: Myocardial infarction, angina, arrhythmias, hypertension
- Respiratory: Bronchospasm
- Endocrine metabolic: Water intoxication syndrome
- Immunologic: Anaphylaxis
- Dermatologic: Gangrenous disorders, sweating, urticaria

Drug interactions:

- Demeclocycline and lithium may decrease antidiuretic effect
- Increased risk of hyponatremia and seizures with polyethylene glycol and sodium phosphate
- Increased antidiuretic effect with carbamazepine and fludrocortisone

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$\$\$\$

## *Nitroglycerin*

Tradenames: Nitroglycerin IV, Nitrostat, Tridil

Manufacturers: American Regent, Baxter, Bristol-Myers-Squibb, Parke-Davis, Quad, Lymphomed

Dosage:

- 10–20 mcg/min continuous i.v. infusion; titrate in increments of 5–10 mcg/min every 5 min to a total dose of 50–180 mcg/min until limiting side effects (headache or hypotension); administer along with vasopressin to prevent vasoconstrictive complications of vasopressin

Contraindications:

- Hypersensitivity to organic nitrates
- Concurrent use of phosphodiesterase inhibitors such as sildenafil or vardenafil (increased hypotensive effect)

- Constrictive pericarditis
- Pericardial tamponade
- Restrictive cardiomyopathy (intravenous)
- Symptomatic hypotension
- Increased intracranial pressure
- Methemoglobinemia

Adverse effects:

- General: Headache, dizziness, flushing
- Cardiac: Hypotension, reflex tachycardia
- Hematological: Methemoglobinemia

Drug interactions:

- Hypotension and cardiovascular collapse with concomitant use of phosphodiesterase inhibitors

Pregnancy category: C

Lactation: Safety unknown

Relative cost: \$

### ***Propranolol***

Brand name: Inderal, Inderal LA, InnoPran XL

Class: beta-adrenergic blockers, nonselective

Manufacturer: Generic

Dosage: Prevention of variceal bleeding: initiate 20 mg p.o. q.12h., adjusting dose q3-4d until heart rate is reduced by 25%, provided it does not drop below 55 bpm

Contraindications:

- Bronchial asthma or chronic obstructive pulmonary disease
- Cardiogenic shock
- Hypersensitivity to propranolol
- Overt cardiac failure
- Second and third degree AV block
- Severe sinus bradycardia

Adverse effects:

- Gastrointestinal: Nausea, vomiting
- Neurologic: Fatigue, insomnia, anesthesia
- Cardiovascular: Bradyarrhythmia, hypotension
- Respiratory: Asthma, bronchospasm
- Dermatologic: Dermatitis, pruritus, urticaria
- Psychiatric: Depression, psychotic disorder

Drug interactions:

- Contraindicated with thioridazines because of risk of AV block, bradycardia, and hypotension
- Caution with haloperidol, amiodarone, digoxin, octreotide: Increased risk of hypotension, bradycardia, and cardiac conduction abnormalities

Pregnancy category: C

Lactation: Probably safe

Relative cost: \$\$

### *Nadolol*

Brand name: Corgard

Class:  $\beta$ -adrenergic blockers, nonselective

Manufacturer: Generic

Dosage: Prevention of variceal bleeding: initiate 10 mg p.o. q.12h., adjusting dose q3–4d until heart rate is reduced by 25, provided it does not drop below 55 bpm

Contraindications:

- Bronchial asthma or chronic obstructive pulmonary disease
- Cardiogenic shock
- Hypersensitivity to nadolol
- Overt cardiac failure
- Second and third degree AV block
- Severe sinus bradycardia

Adverse effects:

- Gastrointestinal: Abdominal discomfort, constipation, diarrhea, nausea
- Neurologic: Dizziness, fatigue
- Cardiovascular: Bradyarrhythmia, hypotension
- Respiratory: Cough, nasal congestion

Drug interactions:

- Contraindicated with thioridazines because of risk of AV block, bradycardia, and hypotension
- Caution with haloperidol, amiodarone, digoxin, octreotide: Increased risk of hypotension, bradycardia, and cardiac conduction abnormalities

Pregnancy category: C

Lactation: Possibly unsafe

Relative cost: \$\$



# 3

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## General GI Motility Disorders

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*Lisa Rossi, MD*

### *CONTENTS*

IRRITABLE BOWEL SYNDROME  
DIARRHEA  
CONSTIPATION

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### IRRITABLE BOWEL SYNDROME

#### *Dicyclomine Hydrochloride*

Brand name: Bentyl

Manufacturer: Axcan Scandipharm

Dosage: Irritable bowel syndrome: 10–40 mg p.o. q.i.d.

Contraindications/cautions:

- Age < 6 months
- Hypersensitivity
- Active infection
- Breastfeeding
- GI obstruction
- Glaucoma
- Myasthenia gravis
- Obstructive uropathy
- Reflux esophagitis
- Severe ulcerative colitis or toxic megacolon
- Unstable cardiovascular status in acute hemorrhage

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## Adverse effects:

- Gastrointestinal: Constipation, nausea, xerostomia
- Neurologic: Dizziness, somnolence
- Cardiovascular: Tachyarrhythmia
- Renal: Urinary retention
- Dermatologic: Diminished sweating
- Ophthalmic: Blurred vision

## Drug interactions:

- Potassium salts: Anticholinergic drugs decrease GI transit, increase local exposure to potassium, thereby causing ulcerative lesions

Pregnancy category: B

Lactation: Possibly unsafe

Relative cost: \$

### *Hyoscyamine Sulfate*

Brand name: Levsin

Class: Anticholinergics/Antispasmodic

Manufacturer: Schwarz Pharma

## Dosage:

- Irritable bowel syndrome: 0.125–0.25 mg sl/p.o. q.4h. p.r.n.

## Contraindications/cautions:

- Glaucoma
- Hypersensitivity to hyoscyamine products or other anticholinergic drugs
- Intestinal obstruction, intestinal atony (in elderly, debilitated), severe ulcerative colitis, paralytic ileus, toxic megacolon
- Myasthenia gravis
- Obstructive uropathy
- Unstable cardiovascular status in acute hemorrhage

## Adverse effects:

- Gastrointestinal: Xerostomia
- Neurologic: Dizziness, somnolence
- Cardiovascular: Tachyarrhythmia
- Renal: Urinary retention
- Dermatologic: Diminished sweating
- Ophthalmic: Blurred vision, raised intraocular pressure

## Drug interactions:

- Potassium salts: Anticholinergic drugs decrease GI transit, increase local exposure to potassium, thereby causing ulcerative lesions

Pregnancy category: C  
Lactation: Possibly safe  
Relative cost: \$

### *Imipramine*

Brand name: Tofranil  
Class: Tricyclic antidepressants  
Manufacturer: Generic

Dosage:

- Irritable bowel syndrome: 10–100 mg/day p.o.; start low and titrate as necessary

Contraindications/cautions:

- Hypersensitivity to imipramine
- Concomitant use of monoamine oxidase (MAO) inhibitors
- Use in patients during acute recovery after a myocardial infarction

Adverse effects:

- Gastrointestinal: Bloating, constipation, xerostomia
- Neurologic: Asthenia, dizziness, headache, somnolence
- Cardiovascular: Cardiac dysrhythmia, heart block, hypertension, myocardial infarction (rare), orthostatic hypotension, palpitations, syncope
- Renal: Urinary retention
- Endocrine: Weight gain
- Ophthalmic: Blurred vision

Drug interactions:

- Antiarrhythmics, class Ia: Increase risk of QT prolongation and cardiac arrhythmias
- MAO inhibitors: Combination may result in CNS overstimulation, hyperpyrexia, seizures, and death
- Potassium salts: Anticholinergic drugs decrease GI transit, increase local exposure to potassium, thereby causing ulcerative lesions
- Pimozide: Increased risk of CNS depression, psychomotor impairment, QT prolongation

Pregnancy category: D  
Lactation: Probably safe  
Relative cost: \$

### *Amitriptyline*

Brand name: Elavil  
Class: Tricyclic antidepressants

Manufacturer: Generic

Dosage:

- Chronic pain: Start: 0.1 mg/kg p.o. q.h., titrate slowly over 2–3 weeks;  
Max: 150 mg/day

Contraindications/cautions:

- Hypersensitivity
- Concomitant use of MAO inhibitors
- Use in patients during acute recovery after a myocardial infarction
- Concomitant cisapride use

Adverse effects:

- Gastrointestinal: Bloating, constipation, xerostomia
- Neurologic: Asthenia, dizziness, headache, somnolence
- Cardiovascular: Cardiac dysrhythmia, heart block, hypertension, myocardial infarction (rare), orthostatic hypotension, palpitations, syncope
- Endocrine metabolic: Weight gain
- Ophthalmic: Blurred vision

Drug interactions:

- Antiarrhythmics, class Ia: Increase risk of QT prolongation and cardiac arrhythmias
- MAO inhibitors: Combination may result in CNS overstimulation, hyperpyrexia, seizures, and death
- Potassium salts: Anticholinergic drugs decrease GI transit, increase local exposure to potassium, thereby causing ulcerative lesions
- Pimozide: Increase risk of CNS depression, psychomotor impairment, QT prolongation

Pregnancy category: D

Lactation: Probably unsafe

Relative cost: \$

## DIARRHEA

Diphenoxylate Hydrochloride/Atropine Sulfate

Brand name: Lomotil

Class: Antidiarrheals

Manufacturer: Pfizer U.S. Pharmaceuticals

Dosage:

- Diarrhea; adjunct: 2 tablets or 10 ml solution p.o. q.i.d. (maximum dose, 20 mg/day (diphenoxylate))

Contraindications/cautions:

- Diarrhea associated with enterotoxin producing bacteria or pseudomembranous enterocolitis; may prolong and/or worsen diarrhea

- Hypersensitivity to diphenoxylate or atropine products
- Obstructive jaundice, may precipitate hepatic coma

Adverse effects:

- Gastrointestinal: Abdominal discomfort, nausea and vomiting, pancreatitis, toxic megacolon
- Neurologic: Dizziness, sedation, somnolence
- Psychiatric: Euphoria

Drug interactions:

- Potassium salts: Anticholinergic drugs decrease GI transit, increase local exposure to potassium, thereby causing ulcerative lesions.

Pregnancy category: C

Lactation: Probably safe

Relative cost: \$

### *Loperamide*

Brand name: Imodium

Class: Antidiarrheals

Manufacturer: Janssen, L.P.

Dosage:

- Diarrhea: 4 mg p.o. after first loose stool initially; then 2 mg after each subsequent stool; not to exceed 16 mg/day

Contraindications/cautions:

- Abdominal pain in the absence of diarrhea
- Bacterial enterocolitis, caused by invasive organisms, including Salmonella, Shigella, and Campylobacter; do not use as primary therapy
- Dysentery, acute; do not use as primary therapy
- Hypersensitivity to loperamide or to any of the excipients
- Infants below 24 months of age
- Pseudomembranous colitis, associated with the use of broad spectrum antibiotics

Adverse effects:

- Gastrointestinal: Abdominal pain, nausea, vomiting, xerostomia, necrotizing enterocolitis in fetus or newborn (rare)
- Neurologic: Dizziness, somnolence, fatigue
- Endocrine: Hyperglycemia

Drug interactions:

- Potassium salts: Anticholinergic drugs decrease GI transit, increase local exposure to potassium, thereby causing ulcerative lesions

Pregnancy category: C  
Lactation: Probably safe  
Relative cost: \$

## CONSTIPATION

### *Alosetron*

Brand name: Lotronex  
Class: Serotonin (5-HT<sub>3</sub>) receptor antagonists  
Manufacturer: GlaxoSmithKline

#### Dosage:

- Restricted access in the US: Irritable bowel syndrome, 0.5 mg p.o. b.i.d. (in women only) for 4 weeks; after 4 weeks of 0.5 mg, may increase to 1 mg b.i.d.

#### Contraindications/cautions:

- Hypersensitivity
- Preexisting constipation; do not initiate therapy
- Concurrent use of fluvoxamine; increases alosetron plasma concentrations and half-life
- History of Crohn's disease, diverticulitis, GI perforation and/or adhesions, impaired intestinal circulation or ischemic colitis, intestinal obstruction, intestinal stricture, or toxic megacolon
- Severe hepatic impairment; alosetron is extensively metabolized in the liver
- History of hypercoagulable state, thrombophlebitis
- Patients unable to understand or comply with Patient-Physician Agreement

#### Side effects:

- Gastrointestinal: Abdominal pain, constipation, nausea, ischemic colitis
- Neurologic: Headache (rare)

#### Drug interactions:

- Fluvoxamine: Increases alosetron levels and increase risk of adverse effects

Pregnancy category: B  
Lactation: Safety unknown  
Relative cost: \$\$\$

### *Lubiprostone*

Brand name: Amitiza  
Class: Chloride-channel activator, laxative  
Manufacturer: Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals America, Inc.

## Dosage:

- Idiopathic constipation, chronic: 24 mcg p.o. b.i.d. with food

## Contraindications/cautions:

- Hypersensitivity
- History of mechanical GI obstruction

## Adverse effects:

- Gastrointestinal: Abdominal distension, abdominal pain, diarrhea, flatulence, nausea
- Neurologic: Headache

## Pregnancy category: C

Lactation: Safety unknown

Relative cost: \$\$

### *Psyllium*

Brand name: Metamucil, Fiberall

Class: Laxative

Manufacturer: Psyllium – Generic, Metamucil – Procter and Gamble Pharmaceuticals

## Dosage:

- Constipation: 15–60 g/day p.o. with at least 8 glasses of water

## Contraindications:

- Hypersensitivity to psyllium
- Intestinal obstruction
- Fecal impaction

## Adverse effects:

- Gastrointestinal: Abdominal distention and flatulence
- Immunologic: Potentially severe (but rare) allergic reactions, anaphylaxis, and asthma

Drug interactions: No major drug interactions known

Pregnancy category: Likely safe

Lactation: Safety unknown, probably safe

Relative cost: \$

### *Methylcellulose*

Brand name: Citrucel

Class: Laxative

Manufacturer: GlaxoSmithKline

## Dosage:

- Constipation: 15–60 g/day p.o. with at least 8 glasses of water

**Contraindications:**

- Hypersensitivity to psyllium
- Intestinal obstruction
- Fecal impaction

**Adverse effects:**

- Gastrointestinal: Abdominal distention and flatulence, nausea

Drug interactions: No major drug interactions

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$

### ***Docusate***

Brand name: Docusate sodium (Colace)/Docusate calcium (Surfak)

Class: Emollient stool softeners

Manufacturer: olace – Roberts Pharmaceutical Corp., Docusate – Generic

**Dosage:**

- Constipation: 100 mg p.o. q.d./b.i.d. (50–200 mg) or 50–100 mg rectally as an enema

**Contraindications:**

- Hypersensitivity to psyllium
- Intestinal obstruction
- Concomitant use of mineral oil
- Acute abdominal pain, nausea, vomiting

**Adverse effects:**

- Gastrointestinal: Abnormal taste in mouth, diarrhea, nausea
- Musculoskeletal: Cramps

**Drug interactions:**

- Mineral oil: Increase mineral oil absorption and adverse effects

Pregnancy category: C

Lactation: Safety unknown

Relative cost: \$

### ***Magnesium Citrate***

Brand name: Evac-Q-Mag

Class: Saline laxatives

Manufacturer: Generic



## Dosage:

- Constipation: 150–300 ml/day or 11–18 g p.o. divided q.d.–b.i.d. (1 ml Mg citrate contains 9.4 mg elemental Mg)
- Preparation of bowel for procedure: 150–300 ml p.o. once, may repeat as needed

## Contraindications/cautions:

- Abdominal pain, nausea/vomiting, rectal bleeding
- Heart block
- Low-salt diet
- Severe renal disease

## Adverse effects:

- Gastrointestinal: Diarrhea
- Neurologic: Asthenia, dizziness
- Respiratory: Hypoventilation

## Drug interactions:

- Doxercalciferol: Increase risk of hypermagnesemia

## Pregnancy category: B

## Lactation: Probably safe

## Relative cost: \$

### *Mineral Oil*

Brand name: Fleet, Zymenol

Class: Lubricant laxative

Manufacturer: Generic

## Dosage:

- Constipation: 15–45 ml p.o. once daily at bedtime, maximum 45 ml or enema – 1 bottle (133 ml) into rectum once.

## Contraindications/cautions:

- Hypersensitivity to psyllium
- Children less than 2 years of age (rectal administration)
- Children less than 6 years of age (oral administration)
- Colostomy/ileostomy
- Diverticulitis, appendicitis
- Ulcerative colitis, rectal bleeding

## Adverse effects:

- Gastrointestinal: Incontinence of feces, intestinal malabsorption, fat-soluble vitamins, rectal discharge, rectal bleeding
- Dermatologic: Anal irritation, pruritus ani
- Other: Chronic abuse of laxatives is accompanied by concerns of lipid pneumonia, lymphoid hyperplasia, and foreign-body reactions

Drug interactions:

- Docusate: Increase mineral oil absorption and adverse effects

Pregnancy category: C

Lactation: Possibly unsafe

Relative cost: \$

### ***Polyethylene Glycol Solution***

Brand name: Glycolax, Miralax

Class: Osmotic laxatives

Manufacturer: Miralax: Schering-Plough; Glycolax: Kremers Urban, LLC;

Polyethylene glycol: Generic

Dosage:

- Constipation: 17 g (about 1 heaping tablespoon) per day dissolved in 4–8 ounces of water, juice, soda, coffee, or tea
- Preparation of bowel for procedure: Polyethylene glycol/electrolytes (Golytely) – 4 l p.o. once

Contraindications/cautions:

- Hypersensitivity to any component, such as polyethylene glycol
- Bowel obstruction, known or suspected

Adverse effects:

- Gastrointestinal: Diarrhea, flatulence, nausea, stomach cramps, bloating

Drug interactions: No major interactions

Pregnancy category: C

Lactation: Probably unsafe

Relative cost: \$

### ***Lactulose***

Please see Chap. 10 for drug details.

### ***Senna***

Brand name: Senokot, Ex-Lax, Senexon, Senna-Gen

Class: Stimulant laxatives

Manufacturer: Senokot – Purdue Pharma; Ex-lax – Novartis Consumer Health;

Senna – Generic

Dosage:

- Constipation: 0.12–0.25 g/day p.o. (2–4 tablets p.o. q.d.–b.i.d.)

**Contraindications/cautions:**

- Acute surgical abdomen
- Bowel obstruction
- Fecal impaction
- Hypersensitivity to anthraquinone laxatives or to any of the ingredients
- Patients with nausea, vomiting, or other symptoms of appendicitis
- Undiagnosed abdominal pain

**Adverse effects:**

- Gastrointestinal: Abdominal pain, nausea, abdominal bloating, abdominal cramps, flatulence, diarrhea, pseudomelanosis coli, cathartic colon
- Renal: Urine discoloration, nephritis
- Other: Laxative abuse

Pregnancy category: C

Lactation: Probably safe

Relative cost: \$

### ***Bisacodyl***

Brand name: Bisac-Evac, Bisco-Lax, Dulcolax, Dacodyl

Class: Stimulant laxatives

Manufacturer: Dulcolax – Boehringer-Ingelheim Consumer Healthcare, Bisacodyl – Generic

**Dosage:**

- Constipation: 5–15 mg p.o. once daily up to 30 mg/day or 10 mg suppository rectally once daily

**Contraindications/cautions:**

- Hypersensitivity to drug
- Nausea, vomiting
- Intestinal obstruction

**Adverse effects:**

- Gastrointestinal: Abdominal colic, abdominal discomfort, diarrhea, proctitis (with suppository use), atony of colon

Pregnancy category: C

Lactation: safety unknown

Relative cost: \$

### ***Castor Oil***

Brand name: Alphamul, Emulsoil, Neoloid, Purge

Class: Stimulant laxatives

Manufacturer: Generic

Dosage:

- Constipation: 15–60 ml p.o. once daily

Contraindications/cautions:

- Hypersensitivity to drug
- Intestinal obstruction
- Acute abdominal pain, nausea, vomiting
- Symptoms of appendicitis
- Pregnancy

Adverse effects:

- Gastrointestinal: Abdominal pain, nausea, vomiting
- Musculoskeletal: Cramps

Pregnancy category: X

Lactation: Possibly unsafe

Relative cost: \$

# 4

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## Specific GI Motility Disorders

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*and Shishir Mathur, MBBS*

### CONTENTS

ACHALASIA, DIFFUSE ESOPHAGEAL SPASM  
(DES)  
GASTROPARESIS  
DUMPING SYNDROME AND ACCELERATED  
GASTRIC EMPTYING  
RAPID TRANSIT DYSMOTILITY OF THE SMALL  
BOWEL

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### ACHALASIA, DIFFUSE ESOPHAGEAL SPASM (DES)

#### *Nifedipine*

Trade names: Adalat CC, Procardia, Procardia XL, Afeditab CR, Nifediac CC, Nifedical XL

Manufacturer: Bayer

Dosages:

- Achalasia: Doses ranging from 10–30 mg p.o. q.d. may provide minimal benefit
- DES: Doses ranging 10–30 mg p.o. q.d.

Contraindications:

- Hypersensitivity to nifedipine and structurally related calcium channel antagonists

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- Caution after acute myocardial infarction (within 4 weeks), congestive heart failure, peripheral edema, hypotension, unstable angina pectoris

Adverse effects:

- Gastrointestinal: Constipation, heartburn, nausea
- Neurologic: Dizziness, headache
- Cardiovascular: Palpitations, peripheral edema, worsening of angina, myocardial infarction (rare)
- Dermatologic: Flushing

Drug interactions:

- Increased risk of AV block, bradycardia, hypotension with octreotide,  $\beta$ -blockers, and amiodarone
- Increased risk of hypotension with nitrates

Pregnancy category: C

Lactation: Probably safe

Relative cost: \$\$

### ***Botulinum Toxin***

Trade names: Botox, Botox Cosmetic

Manufacturer: Allergan, Inc.

Dosage:

- Achalasia: 80–100 units injected into lower esophageal sphincter

Contraindications:

- Anaphylaxis

Adverse effects:

- Gastrointestinal: Dysphagia, indigestion
- Neurologic: Headache, ptosis of eyelid, focal facial paralysis, speech disturbance
- Cardiac: Arrhythmias, hypertension, myocardial infarction, syncope
- Respiratory: Upper respiratory infection, dyspnea
- Musculoskeletal: Muscle weakness, neck pain
- Dermatologic: Injection site pain, erythema multiforme
- Ophthalmic: Dry eyes, acute angle closure glaucoma, punctate keratitis, visual disturbance
- Immunologic: Anaphylaxis (rare)
- Other: Fever, influenza

Drug interactions:

- Clindamycin, aminoglycosides, and succinylcholine may potentiate neuromuscular effects of botulinum toxin

Pregnancy category: C  
Lactation: Safety unknown  
Relative cost: \$\$\$

## GASTROPARESIS

### *Erythromycin*

Trade names: E-Mycin, E.E.S.-200, E.E.S.-400, Ery-Tab, Eryc, EryPed, Erythrocin Stearate Filmtab, Erythrocot, Ilosone, MY-E, PCE Dispertab, Robimycin

Dosages:

- Gastroparesis: 3 mg/kg i.v. q. 8 h. 40–80 mg p.o. t.i.d. before meals
- *Vibrio cholerae* diarrhea: Erythromycin 250 mg p.o. q.i.d. for 3 days
- Campylobacter gastroenteritis: Erythromycin 500 mg p.o. b.i.d. for 5 days

Contraindications:

- Concomitant therapy with astemizole, cisapride, pimozone, or terfenadine
- Hypersensitivity to erythromycin or any component of the product

Adverse effects:

- Gastrointestinal: Diarrhea, loss of appetite, nausea, abdominal cramps, vomiting, aminotransferase elevations, hepatitis, jaundice
- Neurological: Exacerbation of myasthenia gravis, convulsions
- Cardiovascular: Arrhythmias, QT prolongation, torsades de pointes
- Dermatologic: Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme
- Immunologic: Anaphylaxis
- Otic: Reversible hearing loss

Drug interactions:

- Phenothiazines, cisapride, dofetilide, pimozone, ranolazine: Increased risk of QT prolongation and cardiac arrhythmias
- Ergot alkaloids: Increased risk of ergot toxicity, severe localized vasospasm, and ischemia

Pregnancy category: B  
Lactation: Probably safe  
Relative cost: \$

### *Metoclopramide*

Trade name: Reglan  
Manufacturer: Wyeth, Schwarz Pharma

## Dosage:

- Gastroparesis: 5–20 mg p.o. q.i.d.

## Contraindications:

- Concomitant use of drugs with extrapyramidal adverse effects
- GI hemorrhage, obstruction (mechanical), or perforation
- Hypersensitivity to metoclopramide products
- Pheochromocytoma
- Seizure disorders

## Adverse effects:

- Gastrointestinal: Constipation
- Neurologic: Dystonia, sedation, somnolence, tremor, neuroleptic malignant syndrome
- Cardiovascular: Cardiac arrhythmia
- Endocrine metabolic: Body fluid retention
- Psychiatric: Restlessness
- Other: Fatigue

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$

## DUMPING SYNDROME AND ACCELERATED GASTRIC EMPTYING

### *Octreotide*

Please see Chap. 2 for drug information

## RAPID TRANSIT DYSMOTILITY OF THE SMALL BOWEL

### *Loperamide*

Trade name: Diamode, Imodium, Imodium A–D, Imogen, Imotil, Imperim, Kao-Paverin Caps, Kaodene A–D

Manufacturer: Multiple

## Dosage:

- Rapid transit: Loperamide 4 mg t.i.d. and q.h.s.

## Adverse Effects:

- Gastrointestinal: Abdominal pain, nausea, vomiting, xerostomia, necrotizing enterocolitis in fetus or newborn (rare)
- Neurologic: Dizziness, somnolence



- Endocrine metabolic: Hyperglycemia
- Other: Fatigue

Drug interactions:

- Potassium salts: Anticholinergic drugs decrease GI transit, increase local exposure to potassium, thereby causing ulcerative lesions

Pregnancy Category: B

Lactation: Probably safe

Relative cost: \$

# 5

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## Inflammatory Bowel Disease

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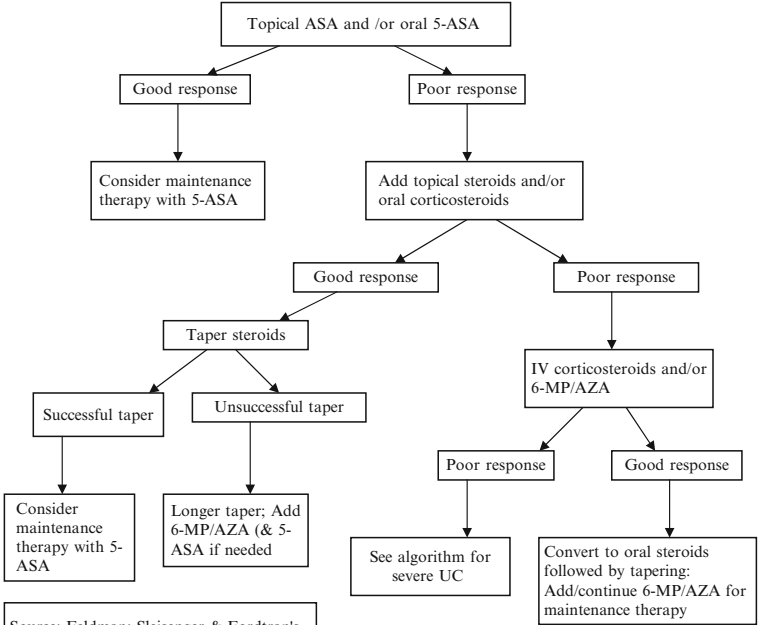
### *CONTENTS*

MILD TO MODERATE ULCERATIVE COLITIS  
SEVERE ULCERATIVE COLITIS  
MILD TO MODERATE CROHN'S DISEASE (CD)

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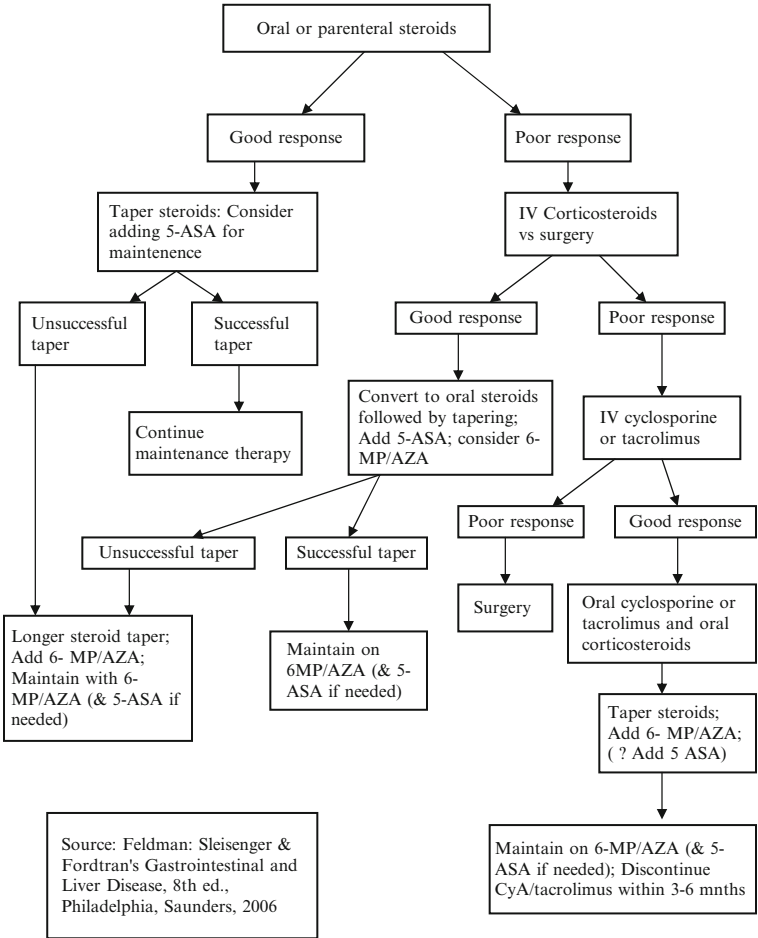
From: *Clinical Gastroenterology: Pocket Handbook of GI Pharmacotherapeutics*  
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### MILD TO MODERATE ULCERATIVE COLITIS

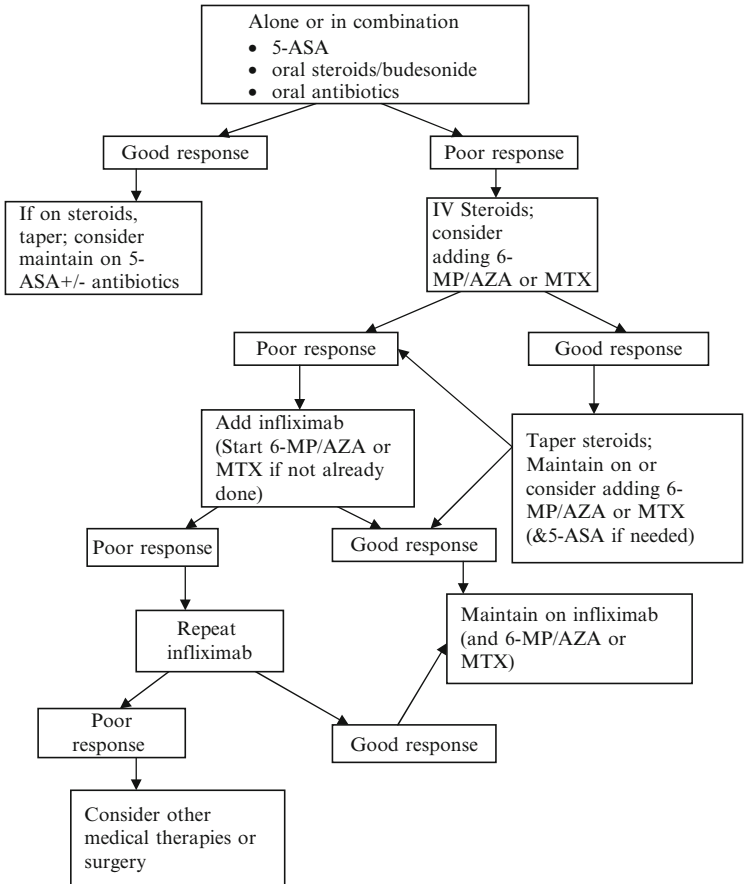


Source: Feldman; Sleisenger & Fordtran's Gastrointestinal and Liver Disease, 8th ed., Philadelphia, Saunders, 2006

### SEVERE ULCERATIVE COLITIS



## MILD TO MODERATE CROHN'S DISEASE (CD)



Source: Feldman: Sleisenger & Fordtran's Gastrointestinal and Liver Disease, 8th ed., Philadelphia, Saunders, 2006

### *Sulfasalazine*

Brand names: Azulfidine, Azulfidine Entabs, Sulfazine, Sulfazine EC

Manufacturer: Sulfasalazine – Generic, Azulfidine – Pfizer U.S. Pharmaceuticals

Dosages:

- Ulcerative colitis – initially, 3–4 g/day p.o. in evenly divided doses not exceeding 8-h intervals; maintenance, 2 g/day p.o. in divided doses not exceeding 8-h intervals

Contraindications/cautions:

- Hypersensitivity to sulfasalazine, sulfa drugs, salicylates
- Intestinal or urinary obstruction
- Porphyria

Adverse effects:

- Gastrointestinal: Anorexia, dyspepsia, nausea, vomiting
- Neurologic: Headache
- Reproductive: Reversible oligozoospermia
- Hematologic: Hemolysis, neutropenia, agranulocytosis, folate deficiency
- Dermatologic: Rash
- Others (rare): Pulmonary infiltrate, nephritis, hepatitis

Drug interactions:

- Methenamine – may produce insoluble precipitate in urine

Pregnancy category: B

Lactation: Safety unknown

Relative cost: \$\$

### *Mesalamine*

Brand names: Asacol, Canasa, Pentasa, Rowasa, Lialda

Manufacturer:

- Asacol – Procter and Gamble Pharmaceuticals
- Pentasa – Shire Pharmaceuticals
- Rowasa – Solvay Pharmaceuticals, Inc.
- Canasa – Axcan Pharma
- Lialda – Shire Pharmaceuticals

Dosage:

- Crohn's disease: 1,000 mg p.o. q.i.d.
- Ulcerative colitis: Chronic, active, and maintenance of remission, 800 mg tablet p.o. t.i.d. (Asacol), 1,000 mg p.o. q.i.d. (Pentasa), 4 g rectally as a retention enema administered at night and retained for 8h. for 3–6 weeks (Rowasa), 2.4–4.8 g p.o. q.d. (Lialda)

**Contraindications/cautions:**

- Hypersensitivity to mesalamine or salicylates
- Active peptic ulcer disease

**Adverse effects:**

- Gastrointestinal: Abdominal pain, constipation, diarrhea, nausea, vomiting, hepatitis
- Neurologic: Asthenia, dizziness, headache
- Musculoskeletal: Arthralgia
- Dermatologic: Pruritus, urticaria
- Others (rare): Paradoxical exacerbation of inflammatory bowel disease, pancreatitis, pericarditis, pneumonitis, nephritis

**Drug interactions:**

- Azathioprine or 6-MP: May increase risk of myelosuppression

Pregnancy category: B

Lactation: Possibly unsafe

Relative cost: \$\$\$\$

### *Olsalazine*

Brand name: Dipentum

Manufacturer: Pharmacia Corp.

**Dosage:**

- Ulcerative colitis: Maintenance of remission, 500 mg p.o. b.i.d.

**Contraindications/cautions:**

- Hypersensitivity to olsalazine or salicylates

**Adverse effects:**

- Gastrointestinal: Abdominal pain, secretory diarrhea, dyspepsia, nausea
- Neurologic: Headache, blurred vision
- Others (rare): Hypertension, hypotension, pericarditis, hepatitis

**Drug interactions:**

- Azathioprine or 6-MP: May increase the risk of myelosuppression

Pregnancy category: C

Lactation: Possibly unsafe

Relative cost: \$\$\$\$

### *Balsalazide*

Brand name: Colazal

Manufacturer: Salix Pharmaceuticals

## Dosage:

- Active ulcerative colitis: 2.25 g p.o. t.i.d.

## Contraindications/cautions:

- Hypersensitivity to balsalazide, mesalamine, or salicylates

## Adverse effects:

- Gastrointestinal: Abdominal pain, diarrhea, nausea, vomiting
- Neurologic: Headache
- Respiratory: Respiratory tract infection
- Musculoskeletal: Arthralgia

## Drug interactions:

- Increased myelosuppression with mercaptopurine and azathioprine

## Pregnancy category: B

## Lactation: Safety unknown

## Relative cost: \$\$\$\$

***Glucocorticoids (Prednisone, Methylprednisolone)***

## Brand name: Generic

## Manufacturer: Generic

## Dosage:

- Crohn's disease: 40–60 mg/day p.o. only for acute flare for a duration of 6–12 weeks
- Ulcerative colitis: 40–60 mg/day p.o. during acute flares
- Autoimmune hepatitis: If single drug therapy then start with 60 mg p.o. q.d. and taper over 4 weeks to 20 mg q.d. maintenance dose until end point. If combination therapy with azathioprine, then start with 30 mg q.d. and taper over 4 weeks to 10 mg q.d. maintenance dose until endpoint

## Contraindications/cautions:

- Hypersensitivity to prednisone
- Systemic fungal infections
- Caution in congestive heart failure, seizure disorder, diabetes, hypertension, TB infection, osteoporosis

## Adverse effects:

- Gastrointestinal: Nausea, vomiting, dyspepsia, appetite change
- Cardiovascular: Hypertension
- Endocrine metabolic: Body fluid retention, decreased body growth, hypernatremia, osteoporosis, hypercortisolism, hyperglycemia, primary adrenocortical insufficiency
- Immunologic: Immunosuppression
- Dermatologic: Atrophic condition of skin, impaired wound healing



- Psychiatric: Depression, euphoria, mood swings, anxiety
- Ophthalmic: Cataract, glaucoma

Drug interactions:

- Live vaccines: Inadequate immunological vaccine response and increased risk of disseminated infection

Pregnancy category: C

Lactation: Probably safe

Relative cost: \$\$

### ***6-Mercaptopurine***

Brand name: Purinethol (6-mercaptopurine)

Manufacturer: Gate Pharmaceuticals

Dosage:

- Crohn's disease: For induction or maintenance of remission. 75–125 mg p.o. q.d. Start 50 mg p.o. q.d., maximum dose of 1.5 mg/kg/day
- Ulcerative Colitis: For induction or maintenance of remission. 75–125 mg p.o. q.d.. Start 50 mg p.o. q.d., maximum dose of 1.5 mg/kg/day

Contraindications/cautions:

- Hypersensitivity to azathioprine
- Caution with impaired renal function
- Pregnancy

Adverse effects:

- Gastrointestinal: Nausea, vomiting, GI ulceration, pancreatitis, hepatotoxicity
- Renal: Nephrolithiasis, urate nephropathy
- Hematologic: Myelosuppression, anemia
- Immune: Immunosuppression

Drug interactions:

- Live vaccines: Inadequate immunological vaccine response and increased risk of disseminated infection

Pregnancy category: D

Lactation: Safety unknown

Relative cost: \$\$\$

### ***Azathioprine***

Brand names: Azasan, Imuran (Azathioprine)

Manufacturer: Generic

## Dosage:

- Ulcerative colitis: 100–250 mg q.d., start with 50 mg q.d., maximum dose of 2.5 mg/kg/day
- Crohn's disease: 100–250 mg daily, start with 50 mg q.d., maximum dose of 2.5 mg/kg/day

## Contraindications/cautions:

- Hypersensitivity to drug/class/component
- Pregnancy
- Caution if impaired renal function

## Adverse effects:

- Gastrointestinal: GI hypersensitivity reaction, nausea, vomiting, pancreatitis, hepatotoxicity, hepatic veno-occlusive disease
- Hematologic: Leukopenia, megaloblastic anemia, thrombocytopenia, bone marrow suppression
- Immune: Chronic immunosuppression
- Other: Lymphoma, malignancy, infection

## Drug interactions:

- Increased risk of serious infection with leflunomide and TNF blockers
- Increased risk of myelosuppression with ACE inhibitors, clozapine, sulfasalazine, interferon- $\alpha$ , balsalazide, mycophenolate mofetil, and a number of anticancer drugs

Pregnancy category: D

Lactation: Possibly unsafe

Relative cost: \$\$\$

### *Cyclosporine*

Brand name: Cyclosporine, Sandimmune

Manufacturer: Novartis Pharmaceuticals

## Dosages:

- Ulcerative colitis (severe): 2–4 mg/kg/day i.v., 5–10 mg/kg/day p.o.

## Contraindications/cautions:

- Hypersensitivity to cyclosporine
- Caution with impaired liver or renal function

## Adverse effects:

- Gastrointestinal: Gingival hyperplasia, diarrhea, nausea and vomiting, hepatotoxicity, pancreatitis, GI bleed
- Neurologic: Neurotoxicity, intracranial hypertension, headache, tremor, encephalopathy, seizure

- Cardiovascular: Hypertension, myocardial infarction
- Renal: Reversible or irreversible renal insufficiency, hyperkalemia
- Hematological: Leukopenia, thrombocytopenia, hemolytic anemia
- Endocrine: Diabetes mellitus, hirsutism, dyslipidemia, hyperuricemia
- Immune: Allergic reactions, anaphylaxis
- Other: Infections, malignancy, optic disc edema, pruritis

Drug interactions:

- Bosentan: Increased bosentan levels and risk of toxicity and also decreased cyclosporine levels and efficacy

Pregnancy category: C

Lactation: Safety unknown

Relative cost: \$\$\$\$

## *Infliximab*

Brand name: Remicade

Manufacturer: Centocor, Inc.

Dosage:

- Crohn's disease, fistulizing and moderate to severe: 5 mg/kg i.v. over 2h. at week 0, 2, and 6 and then every 8 weeks
- Ulcerative colitis, treatment-refractory: 5 mg/kg i.v. over 2h. at week 0, 2, and 6 and then every 8 weeks

Contraindications/cautions:

- Hypersensitivity to infliximab
- Active infection
- Congestive heart failure; NYHA Class III, IV
- Caution in latent tuberculosis, hepatitis B carrier, chronic infection
- Caution in CNS demyelinating disorder, seizure disorder, vasculitis, or immunosuppressed

Adverse effects:

- Gastrointestinal: Abdominal pain, nausea, vomiting, hepatotoxicity (rare)
- Cardiovascular: Worsening of congestive heart failure, acute coronary syndrome
- Hematologic: Leukopenia, neutropenia, pancytopenia, thrombocytopenia, hepatosplenic T-cell lymphoma
- Immunologic: Complications of infusion, drug-induced lupus erythematosus, delayed hypersensitivity reaction
- Infectious: Opportunistic infection, upper respiratory tract and other infections, disseminated tuberculosis, hepatitis B reactivation

## Drug interactions:

- Live vaccines: Inadequate immunological vaccine response and increased risk of disseminated infection
- Abatacept, anakinra: May increase risk of serious infection

Pregnancy category: B

Lactation: Safety unknown

Relative cost: \$\$\$\$\$

***Adalimumab***

Brand name: Humira

Manufacturer: Abbott Laboratories

## Dosage:

- Crohn's disease (moderate to severe): 160 mg s.c. at week 0 (may administer as four injections in 1 day or two injections daily for two consecutive days), 80 mg s.c. at week 2, then 40 mg s.c. every other week starting at week 4

## Contraindications/cautions:

- Hypersensitivity to infliximab
- Active infection

## Adverse effects:

- Gastrointestinal: Nausea, abdominal pain, elevated liver enzymes
- Neurologic: Headache, demyelinating disease exacerbation
- Cardiovascular: Hypertension, congestive heart failure exacerbation
- Hematologic: Pancytopenia, aplastic anemia
- Immunologic: Anaphylaxis, angioneurotic edema, lupus-like syndrome, flare of rheumatoid arthritis
- Dermatologic: Injection site reaction, erythema multiforme, rash
- Infectious: Tuberculosis reactivation, sepsis, opportunistic infections
- Other: Lymphoma, malignancy

## Drug interactions:

- Live vaccines: Inadequate immunological vaccine response and increased risk of disseminated infection
- Abatacept, anakinra: May increase risk of serious infection

Pregnancy category: B

Lactation: Safety unknown

Relative cost: \$\$\$\$\$

# 6

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## General GI Infections

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*Marcy Coash, MD,  
and Shishir Mathur, MBBS*

### *CONTENTS*

DIVERTICULITIS

CHOLANGITIS

SPONTANEOUS BACTERIAL PERITONITIS (SBP)

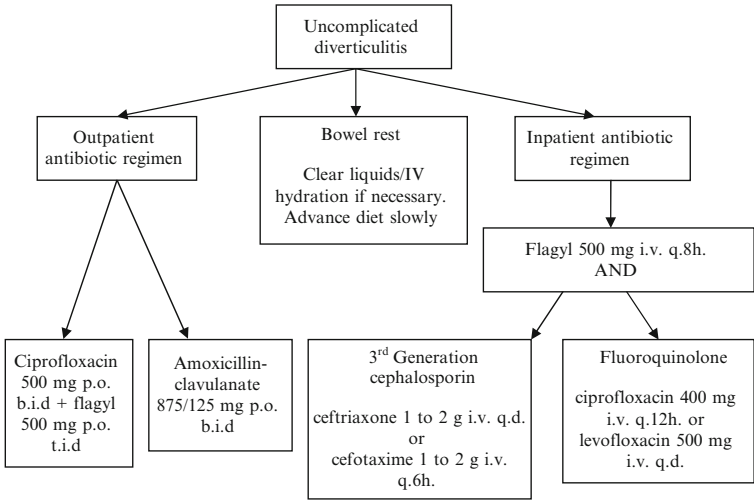
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From: *Clinical Gastroenterology: Pocket Handbook of GI Pharmacotherapeutics*

Edited by: G. Y. Wu and A. Pappano, DOI: 10.1007/978-1-59745-284-7\_6,

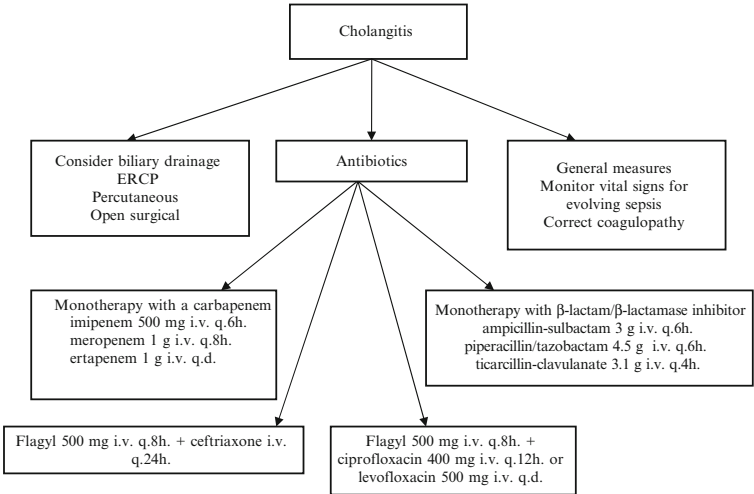
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### DIVERTICULITIS



Source: 2008 UpToDate

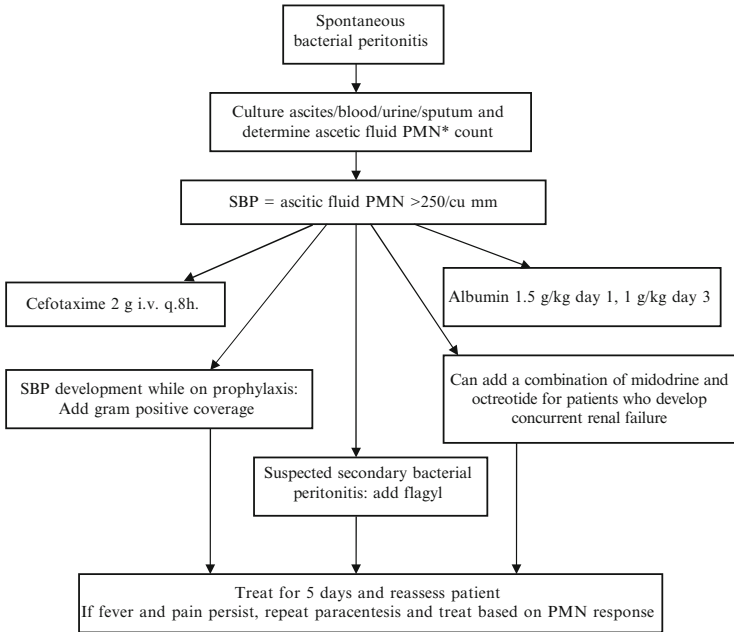
### CHOLANGITIS



\*Treat for 7-10 days although duration should be based on clinical improvement

Source: 2008 UpToDate

## SPONTANEOUS BACTERIAL PERITONITIS (SBP)



\*PMN: polymorphonuclear cells

Source: 2008 UpToDate

Indications for prophylactic antibiotics for prevention of SBP in cirrhosis with ascites:

- Patients with low protein ascites (<1 g/dL) during hospitalization (p.o. or i.v.)
- Previous SBP
- Active variceal hemorrhage (p.o. or i.v.)

### *Cefotaxime*

Brand name: Claforan

Manufacturer: Sanofi-Aventis

Dosages:

- Diverticulitis: 1–2 g i.v. q.6h., maximum 12 g per day, duration varies

Contraindications/cautions:

- Hypersensitivity to drug/class or component of drug
- Impaired renal function or with nephrotoxic agent use
- Seizure disorder
- Hypersensitivity to penicillin

## Adverse effects:

- Gastrointestinal: Nausea, diarrhea, elevated LFTs
- Neurological: Seizures, headache
- Renal: Interstitial nephritis, elevated BUN/creatinine
- Hematological: Neutropenia, hemolytic anemia, thrombocytopenia, agranulocytosis, eosinophilia
- Dermatological: Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis
- General: Fever, pruritis, headache

## Drug interactions:

- Inadequate typhoid vaccine (live oral) response if given within 3 days before or after antibiotic course
- May decrease efficacy of oral contraceptives
- Increased nephrotoxicity with aminoglycosides

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$\$\$\$\$

### *Ceftriaxone*

Brand name: Rocephin

Manufacturer: Roche Laboratories

## Dosages:

- Diverticulitis: 1–2 g i.v. q.24h., maximum 4 g q.24h., duration varies

## Contraindications/cautions:

- Hypersensitivity to drug/class or component of drug
- Parenteral calcium containing product use, concurrent or <48h. after last dose
- Hypersensitivity to penicillin
- Impaired liver and renal function or vitamin K deficiency

## Adverse effects:

- Gastrointestinal: Pseudomembranous colitis, biliary sludge, jaundice
- Respiratory: Bronchospasm, allergic pneumonitis
- Hematological: Neutropenia, leukopenia, hemolytic anemia, thrombocytopenia, hypoprothrombinemia, agranulocytosis
- Immunological: Serum sickness, anaphylaxis

## Drug interactions:

- IV calcium chloride/calcium gluconate may cause calcium ceftriaxone precipitates in lungs, gallbladder
- Inadequate typhoid vaccine (live oral) response if given within 3 days before or after antibiotic course



- May decrease efficacy of oral contraceptives
- Increased nephrotoxicity with aminoglycosides

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$\$\$\$

### *Levofloxacin*

Brand name: Levaquin

Manufacturer: Ortho-McNeil Pharmaceutical

Dosages: 500 mg i.v. q.d.

Contraindications/cautions:

- Hypersensitivity to drug/class or component of drug
- Prolonged QT interval/hypokalemia
- Proarrhythmic conditions
- Seizure or CNS disorders
- Dehydration
- Renal function

Adverse effects:

- Gastrointestinal: Pseudomembranous colitis, hepatotoxicity
- Neurophychiatric: Toxic psychosis, depression, suicidal ideation
- Cardiovascular: Prolonged QT, torsades de pointes
- Renal: Nephrotoxicity
- Immunological: Anaphylaxis, hypersensitivity
- Musculoskeletal: Tendon rupture

Drug interactions:

- Increased risk of QT prolongation with antiarrhythmics, class Ia and class III, cisapride, phenothiazines, ziprasidone, fluconazole, haloperidol, erythromycin, tacrolimus, tricyclic antidepressants

Pregnancy category: C

Lactation: Probably safe

Relative cost: \$\$\$

### *Norfloxacin*

Brand Name: Noroxin

Manufacturer: Merck & Co. Inc.

Dosage:

- SBP prophylaxis: 400 mg p.o. q.d. or b.i.d.

Contraindications/cautions:

- Hypersensitivity to drug/class or component of drug

- Pregnancy
- Breastfeeding
- Safety not established for <18 years old
- Prolonged QT interval

Adverse reactions:

- Gastrointestinal: Pseudomembranous colitis, nausea, vomiting, abdominal pain, elevated LFTs
- Neurological: Seizures
- Cardiac: QT prolongation (rare), torsades de pointes (rare)
- Musculoskeletal: Tendon rupture (rare), arthropathy (animal studies)
- Immunological: Hypersensitivity reaction, anaphylaxis
- Dermatological: Photo toxicity, skin reactions

Drug interactions:

- Increased risk of QT prolongation with antiarrhythmics, class Ia and class III, cisapride, phenothiazines, ziprasidone, fluconazole, haloperidol, erythromycin, tacrolimus, tricyclic antidepressants

Pregnancy category: C

Lactation: Probably safe

Relative cost: \$\$\$

## *Ciprofloxacin*

Brand Names: Cipro, Cipro XR

Manufacturer: Generic

Dosages:

- Infections: 250–750 mg p.o. b.i.d. or 200–400 mg i.v. q.12h.
- SBP prophylaxis: 250–750 mg p.o q.12h. or 200–400 mg i.v. q.12h.

Contraindications/cautions:

- Hypersensitivity to drug/class or component of drug
- QT prolongation
- Seizure disorders

Adverse reactions:

- Gastrointestinal: Nausea, vomiting, diarrhea, abdominal pain, pseudomembranous colitis, hepatotoxicity
- Neurological: Seizures, increased intracranial pressure
- Cardiac: QT prolongation
- Renal: Nephrotoxicity (rare), crystalluria (rare)
- Hematological: Myelosuppression (rare), blood dyscrasias (rare)
- Musculoskeletal: Tendon rupture (rare), arthropathy (animal studies)
- Immunological: Anaphylaxis, vasculitis, serum sickness
- Dermatological: Photosensitivity, skin reactions, phototoxicity, psychosis, peripheral neuropathy

## Drug interactions:

- Increased risk of QT prolongation with antiarrhythmics, class Ia and class III, cisapride, phenothiazines, ziprasidone, fluconazole, haloperidol, erythromycin, tacrolimus, tricyclic antidepressants

Pregnancy category: C

Lactation: Probably safe

Relative cost: \$\$\$

***Sulfamethoxazole and Trimethoprim***

Brand name: Bactrim

Manufacturer: AR Scientific, Inc.

Other brand names: Bethprim, Cotrim, Cotrim DS, Septra, Septra DS, Sulfatrim, Uroplus, Uroplus DS

## Dosage:

- SBP prophylaxis: 160/800 (DS tablet) p.o. q.d.

## Contraindications/cautions:

- Hypersensitivity to drug/class or component of drug
- Megaloblastic anemia
- Folate deficiency
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- Near term pregnancy
- Breastfeeding

## Adverse reactions:

- Gastrointestinal: Nausea, vomiting, hepatic necrosis, pseudomembranous colitis
- Pulmonary: Pulmonary infiltrates
- Renal: Interstitial nephritis, nephrotoxicity, hyperkalemia
- Hematologic: Agranulocytosis, aplastic anemia, blood dyscrasias, methemoglobinemia, myelosuppression
- Immunological: Hypersensitivity reaction
- Dermatologic: Rash, urticaria, photosensitivity, Stevens-Johnson syndrome, toxic epidermal necrolysis

## Drug interactions:

- Methenamine: May produce insoluble precipitate in urine
- Topical benzocaine, butamben, tetracaine, lidocaine, prilocaine: Increased risk of methemoglobinemia

Pregnancy category: C

Lactation: Safety conditional

Relative cost: \$

# 7

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## Specific GI Microbial Infections

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Vivian Teixeira, MD,  
and Shishir Mathur, MBBS*

### *CONTENTS*

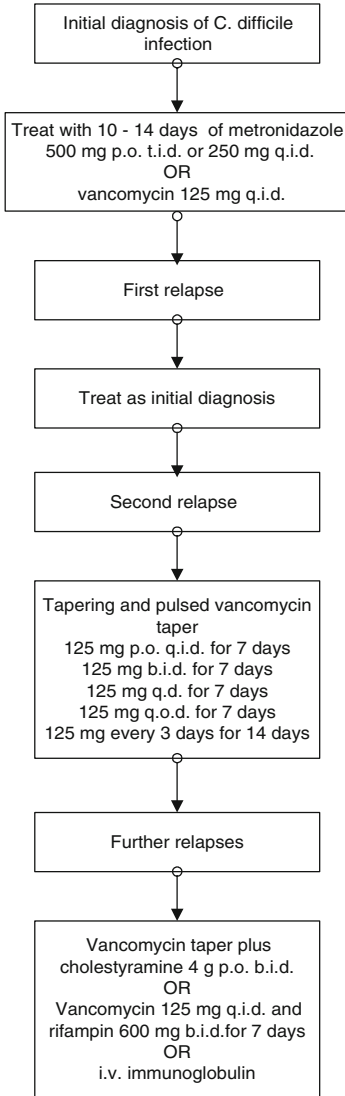
BACTERIAL INFECTIONS  
FUNGAL INFECTIONS  
VIRAL INFECTIONS  
PROTOZOAL INFECTIONS  
PARASITIC INFESTATIONS  
INFECTIVE ENDOCARDITIS PROPHYLAXIS  
FOR GI PROCEDURES

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## BACTERIAL INFECTIONS

### *Clostridium Difficile*



Source: Feldman: Sleisenger & Fordtran's Gastrointestinal and Liver Disease, 8th ed., Philadelphia, Saunders, 2006.

## *Metronidazole*

Brand name: Flagyl

Manufacturer: Searle

Dosages:

- First line in pseudomembranous enterocolitis: 500–750 mg p.o. t.i.d. or 250–500 mg p.o. q.i.d. for 7–14 days. Intravenous metronidazole has been used to treat patients with pseudomembranous colitis who are unable to take the medication orally
- General infections: 500–750 mg p.o. q.6–8h. for 7–14 days
- Amebic liver abscess: 500–750 mg t.i.d. for 5–10 days
- Intestinal amebiasis: 750 mg t.i.d. for 5–10 days
- Giardiasis: 250 mg t.i.d. for 5–7 days or 2 g p.o. q.d. for 3 days

Contraindications/cautions:

- Hypersensitivity to metronidazole, nitroimidazole derivatives, or any component of the formulation
- Pregnancy (first trimester – found to be carcinogenic in rats)
- Caution in blood dyscrasia, liver dysfunction, CNS disorder

Adverse effects:

- Gastrointestinal: Abdominal discomfort, loss of appetite, metallic taste, nausea, and vomiting
- Neurologic: Ataxia, dizziness, headache, peripheral neuropathy, seizure
- Reproductive: Candida infection of genital region, symptomatic cervicitis/vaginitis, vaginal discharge
- Hematologic: Leukopenia, thrombocytopenia
- Immunologic: Jarisch-Herxheimer reaction
- Other: Disulfiram-like reaction with alcohol, ototoxicity

Drug interactions:

- Disulfiram-like reaction with ritonavir, tipranavir, diazoxide
- Increases levels and toxicity of tacrolimus, cyclosporine, lithium, and phenytoin

Pregnancy category: B

Lactation: Safety conditional

Relative cost: \$

## *Vancomycin*

Brand name: Vancocin

Manufacturer: Generic

Dosage:

- Pseudomembranous enterocolitis: 500 mg to 2 g p.o. q.d. divided every 6–8h. for 7–10 days. Intravenous form is ineffective.

**Contraindications/cautions:**

- Hypersensitivity to vancomycin products
- Impaired renal function
- Hearing loss

**Adverse effects:**

- Gastrointestinal: Nausea and vomiting
- Cardiovascular: Hypotension accompanied by flushing
- Renal: Nephrotoxicity (rare)
- Hematologic: Neutropenia (rare)
- Immunologic: Anaphylaxis (rare)
- Dermatologic: Erythematous rash on face and upper body (red neck or red man syndrome – infusion rate related)
- Otic: Ototoxicity (rare)

**Drug interactions:**

- Increased nephrotoxicity with tenofovir, cidofovir, acyclovir, cyclosporine, gancyclovir

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$\$\$\$

### ***Cholestyramine***

Brand name: Prevalite, Questran, Questran Light

Manufacturer: Generic

**Dosage:**

- Bile acid sequestrant. May be used to bind the *C. difficile* toxins for excretion into the feces. 2–4 g p.o. b.i.d.–q.i.d. to a maximum of 16 g/day

**Contraindications/cautions:**

- Complete biliary obstruction
- Hypersensitivity to bile-sequestering resins

**Adverse effects:**

- Gastrointestinal: Abdominal discomfort, constipation, flatulence, nausea and vomiting, fecal impaction
- Hematologic: Clotting and bleeding disorders due to hypoprothrombinemia

**Drug interactions:**

- May decrease efficacy of amiodarone, thyroid hormones, leflunomide, and raloxifene

Pregnancy category: C

Lactation: Safety unknown

Relative cost: \$

## ***Colestipol***

Brand name: Colestid

Manufacturer: Pharmacia Corp.

Dosage:

- Bile acid sequestrant. May be used to bind the *C. difficile* toxins for excretion into the feces, 2–16 g/day, given once or in divided doses orally

Contraindications/cautions:

- Hypersensitivity to colestipol or any other component
- Caution in constipation

Adverse effects

- Gastrointestinal: Constipation, abdominal discomfort, flatulence, indigestion, diarrhea, nausea, vomiting, bleeding hemorrhoids, difficulty swallowing, abnormal liver function tests

Drug interactions:

- May decrease efficacy of amiodarone, thyroid hormones, leflunomide, and raloxifene

Pregnancy category: N/A

Lactation: Safety unknown

Relative cost: \$

## ***E. Coli (EP and EI) Gastroenteritis***

- Ciprofloxacin: 500 mg b.i.d. for 3–5 days. Refer Chap. 7 for drug details
- Bactrim: One double strength tablet b.i.d. for 3–5 days: Refer Chap. 7 for drug details

## ***Shigella Gastroenteritis***

- Ciprofloxacin: Drug of choice – 500 mg p.o. b.i.d. × 5 days. 1 g p.o. once for mild disease due to *Shigella* species other than *S. dysenteriae* 1
- Bactrim: 1 double strength tab (160 mg trimethoprim (TMP)/800 mg sulfamethoxazole (SMX)) p.o. b.i.d. × 5 days
- Azithromycin: 500 mg p.o. q.d. × 1 day, then 250 mg p.o. q.d. × 4 days

## ***Salmonella Gastroenteritis***

1. Usually symptomatic management with fluids and electrolyte replacement
2. In severely ill, immunocompromised adults and children or elderly patients:



- Ciprofloxacin 500 mg p.o. b.i.d. for 3–7 days or
- Levofloxacin 500 mg p.o. q.d. or
- TMP–SMX 160 mg/800 mg p.o. b.i.d. or
- Amoxicillin 500 mg p.o. t.i.d. or
- If intravenous therapy required, a third generation cephalosporin (ceftriaxone 1 to 2 g i.v. q.d. or cefotaxime 2 g i.v. q. 8 h.)

### ***Campylobacter Gastroenteritis***

1. Usually symptomatic management with fluids and electrolyte replacement
2. In severely ill, elderly, pregnant, or immunocompromised patients, and those with bloody stools, high fever, extraintestinal infection, worsening or relapsing symptoms, or symptoms lasting longer than 1 week
  - Erythromycin 500 mg p.o. b.i.d. for 5 days or
  - Ciprofloxacin 500 mg p.o. b.i.d.

### ***Vibrio Cholerae***

1. Usually management with fluids and electrolyte replacement either orally or intravenously
2. As adjunct to appropriate rehydration
  - Tetracycline 500 mg q.i.d. for 3 days or
  - Doxycycline 300 mg once or
  - Erythromycin 250 mg q.i.d. for 3 days or
  - Azithromycin 1,000 mg once or
  - Ciprofloxacin 1,000 mg once

### ***Yersinia Gastroenteritis***

1. Usually symptomatic management with fluids and electrolyte replacement
2. In severely ill, elderly, pregnant, or immunocompromised patients, or those having an underlying comorbid illness
  - Ciprofloxacin 500 mg p.o. b.i.d. for 5 days or
  - TMP–SMX in children (TMP 8 mg/kg/day and SMX 40 mg/kg/day in two divided doses)
  - If septicemia: Ceftriaxone 2 g/day combined with gentamicin 5 mg/kg/day in one to three divided doses for 3 weeks

*Listeria Monocytogenes*

Isolated GI illness does not require antibiotic treatment.

*Whipple's Disease***Overview of Antibiotics Used to Treat Whipple's Disease**

<i>Drug</i>	<i>Dosage</i>	<i>Comments</i>
Penicillin G + streptomycin	6–24 million units i.v. daily (in divided doses) + 1 g i.m. q.d.	Induction therapy (first 10–14 days)
Ceftriaxone	2 g i.v. q.d.	Induction therapy (first 10–14 days) or salvage therapy; less widely used than penicillin G + streptomycin
TMP–SMX	160 mg/800 mg p.o. b.i.d.	Long-term therapy; first line drug; good CNS penetration, but CNS relapses may occur
Penicillin VK	500 mg p.o. q.i.d.	Alternative for long-term therapy; limited experience
Doxycycline (or tetracycline)	100 mg p.o. b.i.d. (500 mg p.o. q.i.d.)	Used for many years, but clinical relapses, including CNS, are well described
Cefixime	400 mg p.o. b.i.d.	Alternative for long-term therapy; limited experience
Rifampin	600 mg p.o. q.d.	Second line drug; good CNS penetration
Chloramphenicol	500 mg p.o. q.i.d.	Second line drug; worrisome side effects
Erythromycin	500 mg p.o. q.i.d.	Second line drug; limited experience
Pefloxacin	400 mg p.o. b.i.d.	Second line drug; limited experience

Source: Feldman: Sleisenger & Fordtran's Gastrointestinal and Liver Disease, 8th ed., Philadelphia, Saunders, 2006

## *Azithromycin*

Brand name: Zithromax

Manufacturer: Pfizer, Inc.

Dosage:

- Shigella and enterohemorrhagic *E. coli* – 500 mg p.o. q.d. × 1 day, then 250 mg p.o. q.d. × 4 days

Contraindications/cautions:

- Hypersensitivity to drug or components
- Caution in impaired renal function, impaired hepatic function
- Caution in QT prolongation

Adverse effects:

- Gastrointestinal: Cholestatic jaundice, pseudomembranous colitis, diarrhea, nausea, abdominal pain, dyspepsia
- Cardiovascular: QT prolongation
- Dermatologic: Angioedema, Stevens-Johnson syndrome, pruritus

Drug interactions:

- Increased risk of QT prolongation with cisapride, phenothiazines, pimozide, ranolazine, antiarrhythmics class IA and class III, chloroquine, droperidol, haloperidol, erythromycin, flecainide, methadone, pentamidine, ziprasidone

Pregnancy: B

Lactation: Safety unknown

Relative cost: \$\$

## *Doxycycline*

Brand names: Adoxa, Doryx, Doxy Lemmon, Doxy-Caps, Doxy-D, Monodox, Oracea, Periostat, Vibra-Tabs, Vibramycin, Vibramycin Calcium, Vibramycin Hyclate, Vibramycin Monohydrate

Manufacturer: Generic

Dosage:

- *Vibrio cholerae* – 300 mg p.o. × 1 day

Contraindications/cautions:

- Hypersensitivity to drug or components
- Children less than 8-years old
- Caution in impaired liver function, impaired renal function
- Avoid sun/UV light exposure
- History of, or predisposition to, candidiasis
- Pregnancy

## Adverse effects:

- Dermatologic: Photosensitivity, skin discoloration, rash, erythema multiforme, Stevens-Johnson syndrome
- Gastrointestinal: Hepatotoxicity, esophagitis, pseudomembranous colitis, pancreatitis, diarrhea, nausea, dyspepsia
- Hematologic: Neutropenia, thrombocytopenia, hemolytic anemia
- Other: Tooth discoloration in children less than 8-years old, headache, joint pain, pericarditis

## Drug interactions:

- Contraindicated with acitretin because of increased risk of pseudotumour cerebri and papilledema
- Increased levels and risk of digoxin, lithium toxicity if given together
- Increased phototoxicity with hydroquinone/retinoic acid combinations

Pregnancy: D

Lactation: Unsafe

Relative cost: \$

### *Tetracycline*

Brand name: Sumycin

Manufacturer: Generic

Dosage: 1–2 g/day p.o. divided b.i.d.–q.i.d. Give at least 1 h. before or 2 h. after meals

## Contraindications/cautions:

- Hypersensitivity to drug or components
- Caution in impaired renal function, impaired hepatic function
- Caution in systemic lupus erythematosus
- Pregnancy

## Adverse effects:

- Gastrointestinal: Hepatotoxicity, pseudomembranous colitis, pancreatitis, diarrhea, nausea, dyspepsia, abdominal discomfort
- Hematologic: Neutropenia, thrombocytopenia, hemolytic anemia
- Dermatologic: Photosensitivity, skin discoloration, rash, erythema multiforme, Stevens-Johnson syndrome
- Other: Tooth discoloration in less than 8-years old, headache, dizziness

## Drug interactions:

- Contraindicated with acitretin because of increased risk of pseudotumour cerebri and papilledema
- Increased levels and risk of digoxin, lithium toxicity if given together
- Increased phototoxicity with hydroquinone/retinoic acid combinations

Pregnancy: D  
Lactation: Possibly unsafe  
Relative cost: \$

## FUNGAL INFECTIONS

### *Oropharyngeal Candidiasis*

#### 1. HIV-negative patients:

- Topical therapy, with either clotrimazole troches (10 mg troche five times daily or nystatin suspension (200,000–400,000 units five times daily)

#### 2. HIV-positive patients:

- For initial episode of oropharyngeal candidiasis in HIV-infected patients with mild disease – topical therapy
- For patients with recurrent infection, moderate to severe disease, or in those with advanced immunosuppression (CD4 < 100) – fluconazole 200 mg loading dose, followed by 100 mg q.d. for 7–14 days after clinical improvement

### *Esophageal Candidiasis*

- Fluconazole 200 mg loading dose followed by 100 mg p.o. q.d. for 14–21 days
- Voriconazole 200 mg b.i.d.
- If i.v. therapy needed – caspofungin 50 mg i.v. for 7–21 days

### *Cryptosporidium Hominis*

- Nitroxanide 500 mg p.o. b.i.d. for 7 days

See below for drug details.

### *Cyclospora Cayetanensis*

- Bactrim 160/800 mg p.o. b.i.d. for 7 days

Please see Chap. 7 for drug details

### *Clotrimazole*

Brand name: Mycelex Troche  
Manufacturer: Ortho-McNeil Pharmaceutical

**Dosage:**

- Oropharyngeal candidiasis: clotrimazole troches 10 mg p.o. five times a day for 14 days. Do not chew or swallow whole

**Contraindications/cautions:**

- Hypersensitivity to drug or components
- Caution in impaired liver function

**Adverse effects:**

- Gastrointestinal: Nausea, vomiting, abdominal cramps, abnormal liver function tests

**Drug interactions:** No significant drug interactions known

**Pregnancy:** C

**Lactation:** Safety unknown

**Relative cost:** \$\$\$

## ***Fluconazole***

**Brand name:** Diflucan

**Manufacturer:** Pfizer, Inc.

**Dosage:**

- Esophageal candidiasis: 100 mg p.o./i.v. q.d.. Start 200 mg p.o./i.v. × 1 day. Continue for more than 3 weeks total, and for more than 2 weeks after symptom resolution

**Contraindications/cautions:**

- Hypersensitivity to drug or components
- Caution in impaired liver function, renal function
- Caution in QT prolongation, pro-arrhythmic conditions, electrolyte abnormalities, heart disease, elderly

**Adverse effects:**

- Gastrointestinal: Hepatotoxicity, nausea, vomiting, abdominal pain, diarrhea, dyspepsia, taste changes
- Neurologic: Seizures, headache, dizziness
- Cardiac: QT prolongation, torsades de pointes
- Hematologic: Leukopenia, agranulocytosis, thrombocytopenia
- Dermatologic: Stevens-Johnson syndrome, angioedema, rash

**Drug interactions:**

- Decreased levels of antifungal drug with concomitant use of barbiturates, carbamazepine, rifampin, rifabutin
- Increased risk of QT prolongation with cisapride, droperidol, phenothiazines, pimozide, quinidine, ranolazine, amiodarone

Pregnancy: C  
Lactation: Probably safe  
Relative cost: \$\$\$

### *Voriconazole*

Brand name: Vfend  
Manufacturer: Pfizer, Inc.

Dosage:

- Esophageal candidiasis: 200 mg p.o. q.12h. Treat for 14 days minimum and for 7 days after symptom resolution. Give 1h. before or after meal

Contraindications/cautions:

- Hypersensitivity to drug or components
- Caution in impaired liver function, renal function
- Caution in proarrhythmic conditions, electrolyte abnormalities, galactose intolerance, lactase deficiency, hematologic malignancy

Adverse effects:

- Gastrointestinal: Hepatitis, fulminant hepatic failure, nausea, vomiting, diarrhea, abdominal pain, increase in aminotransferases, increase in alkaline phosphatase
- Cardiac: QT prolongation, torsades de pointes, tachycardia
- Dermatologic: Stevens-Johnson syndrome, angioedema, rash
- Other: Color vision changes, photophobia, hallucinations, renal failure, peripheral edema

Drug interactions:

- Decreased levels of antifungal drug with concomitant use of barbiturates, carbamazepine, rifampin, rifabutin
- Increased risk of QT prolongation with cisapride, droperidol, phenothiazines, pimozide, quinidine, ranolazine, amiodarone

Pregnancy: D  
Lactation: Safety unknown  
Relative cost: \$\$\$\$\$

### *Caspofungin*

Brand name: Cancidas  
Manufacturer: Merck & Co., Inc.

Dosage:

- Esophageal candidiasis: 50 mg i.v. q.24h. for 7–21 days

## Contraindications/cautions:

- Hypersensitivity to drug or components
- Caution in impaired liver function

## Adverse effects:

- Gastrointestinal: Hepatotoxicity, nausea, vomiting, diarrhea, abdominal pain, increase in aminotransferases, increase in alkaline phosphatase
- Pulmonary: Adult respiratory distress syndrome, pulmonary edema
- Other: Fever, chills, hypercalcemia, hypokalemia, flushing, eosinophilia

## Drug interactions:

- Cyclosporine may increase caspofungin levels and the risk of hepatotoxicity
- Carbamazepine, dexamethasone, efavirenz, nevirapine, phenytoin, rifabutin, rifampin may decrease caspofungin levels
- Caspofungin may decrease sirolimus, tacrolimus levels

Pregnancy: C

Lactation: Safety unknown

Relative cost: \$\$\$\$

### *Nitazoxanide*

Brand name: Alinia

Manufacturer: Romark Laboratories, LC

## Dosage:

- Infectious diarrhea: 500 mg p.o. q.12h. for 3 days. Give with food
- *Cryptosporidium hominis*: 500 mg p.o. b.i.d. for 7 days

## Contraindications/cautions:

- Hypersensitivity to drug or components
- Caution in impaired liver function, renal function
- Caution in biliary disease, diabetes, HIV, immunodeficiency

## Adverse effects:

- Gastrointestinal: Abdominal pain, diarrhea, nausea
- Other: Headache

## Drug interactions:

- May increase levels of warfarin and phenytoin

Pregnancy: B

Lactation: Safety unknown

Relative cost: \$\$\$



## VIRAL INFECTIONS

### *Cytomegalovirus (CMV) Gastrointestinal Disease*

- Ganciclovir (5 mg/kg p.o. b.i.d.) or foscarnet (90 mg/kg b.i.d.) for induction therapy for 3–6 weeks
- Switch to oral valganciclovir (900 mg p.o. b.i.d.) to complete induction therapy once the presenting clinical manifestations have resolved

### *Herpes Simplex Esophagitis*

- Acyclovir 400 mg p.o. five times a day for 14–21 days
- If unable to swallow – Acyclovir 5 mg/kg i.v. q.8h. for 7–14 days or i.v. foscarnet 40 mg/kg/dose every 8–12 h. for 14–21 days

### *Ganciclovir*

Brand name: Cytovene

Manufacturer: Roche Laboratories

Dosage:

- CMV prophylaxis in solid organ transplant: 5 mg/kg i.v. q.12h. for 7–14 days, then 5 mg/kg i.v. q.24h. seven times a week or 6 mg/kg q.24h. five times a week. Alternative: 1,000 mg p.o. t.i.d. Give with food
- CMV gastrointestinal disease: 5 mg/kg i.v. b.i.d. × 3–6 weeks for induction therapy

Contraindications/cautions:

- Hypersensitivity to drug or components
- Hypersensitivity to acyclovir
- Absolute neutrophil count less than 500/mm<sup>3</sup>
- Platelets less than 25,000/mm<sup>3</sup>
- Caution in impaired renal function
- Caution in myelosuppression, elderly

Adverse effects:

- Gastrointestinal: Pancreatitis, perforation, diarrhea, vomiting, increased liver aminotransferases
- Neurologic: Seizures, neuropathy
- Hematologic: Pancytopenia, anemia
- Other: Depression, retinal detachment, hypertension, nephrotoxicity, impaired fertility, fever

Drug interactions:

- Increased risk of nephrotoxicity with cidofovir, aminoglycosides, carboplatin, cisplatin, clofarabine, efavirenz/emtricitabine/tenofovir, tacrolimus

- Increased risk of myelosuppression with clozapine, azathioprine, cisplatin, methotrexate
- Increased risk of seizures with imipenem

Pregnancy: C

Lactation: Unsafe

Relative cost: \$\$\$

### *Valganciclovir*

Brand name: Valcyte

Manufacturer: Roche Laboratories

Dosage:

- CMV colitis: 900 mg p.o. q.d. for 14–21 days

Contraindications/cautions:

- Hypersensitivity to drug or components
- Hypersensitivity to ganciclovir
- Absolute neutrophil count less than 500/mm<sup>3</sup>
- Hemoglobin less than 8 mg/dl
- Platelets less than 25,000/mm<sup>3</sup>
- Caution in impaired renal function
- Caution in myelosuppression, elderly, chemotherapy, pregnancy

Adverse effects:

- Gastrointestinal: Diarrhea, vomiting, abdominal pain
- Neurologic: Seizures, neuropathy, agitation, psychosis
- Hematologic: Aplastic anemia, leukopenia, thrombocytopenia, neutropenia, myelosuppression
- Other: Infertility, nephrotoxicity

Drug interactions:

- Increased risk of nephrotoxicity with cidofovir, aminoglycosides, carboplatin, cisplatin, clofarabine, efavirenz/emtricitabine/tenofovir, tacrolimus
- Increased risk of myelosuppression with clozapine, azathioprine, cisplatin, methotrexate
- Increased risk of seizures with imipenem

Pregnancy: C

Lactation: Unsafe

Relative cost: \$\$\$\$

### *Foscarnet*

Brand name: Foscavir

Manufacturer: AstraZeneca Pharmaceuticals, LP

## Dosage:

- CMV colitis – 60 mg/kg q.8h. or 90 mg/kg q.12h. for 2 weeks as infusion, followed by maintenance regimens of 90–120 mg/kg q.d.

## Contraindications/cautions:

- Hypersensitivity to drug or components
- Caution in impaired renal function
- Caution in myelosuppression, seizure, cardiac disease, electrolyte abnormalities, combination with nephrotoxic agents

## Adverse effects:

- Gastrointestinal: Pancreatitis, nausea, vomiting, diarrhea
- Neurologic: Paresthesia
- Hematologic: Anemia, granulocytopenia, leukopenia, thrombocytopenia
- Other: Hypomagnesemia, hypokalemia, hypocalcemia, nephrotoxicity, fever

## Drug interactions:

- Increased nephrotoxicity with cidofovir, aminoglycosides, carboplatin, cisplatin, clofarabine, efavirenz/emtricitabine/tenofovir, gallium, tenofovir
- May cause QT prolongation with droperidol, erythromycin, amiodarone

Pregnancy: C

Lactation: Safety unknown

Relative cost: \$\$\$\$\$

## PROTOZOAL INFECTIONS

### *Antihelminthic Therapies*

<i>Infection</i>	<i>Treatment of Choice</i>	<i>Alternative Treatments</i>
Angiostrongyliasis	Supportive and corticosteroids	
Ascariasis	Mebendazole 100 mg b.i.d. for 3 days	Pyrantel pamoate 11 mg/kg or albendazole 400 mg once
Cutaneous larva migrans	Ivermectin 200 mg/kg daily for 1–2 days	Albendazole 400 mg once daily for 3 days
Cysticercosis	Albendazole 400 mg b.i.d. for 8–30 days Concurrent steroids for CNS disease	Praziquantel 50–100 mg/kg/day in 3 doses × 30 days
Dracunculiasis	Metronidazole 250 mg t.i.d. for 10 days plus worm removal	

(continued)

## (continued)

<i>Infection</i>	<i>Treatment of Choice</i>	<i>Alternative Treatments</i>
Echinococcosis/ Hydatid cyst	Perioperative albendazole	Albendazole 400 mg b.i.d. for 1–6 months
Enterobiasis/ pinworm	Pyrantel pamoate 11 mg/kg once or albendazole 400 mg once or mebenda- zole 100 mg once Repeat after 2 weeks	
Hook worm/ Ancylostomiasis	Albendazole 400 mg once or mebendazole 100 mg b.i.d. for 3 days or pyr- antel pamoate 11 mg/kg for 3 days	
Onchocerciasis	Ivermectin 150 mg/kg once, repeat every 6–12 months	
<i>Fluke infections</i>		
Liver flukes	Praziquantel 75 mg/kg/day in 3 doses for 1 day	
Intestinal flukes		
Lung fluke	Praziquantel 75 mg/kg/day in 3 doses for 2 days	
Sheep liver fluke	Triclabendazole 10 mg/kg once	
<i>Schistosomiasis</i>		
<i>S. mansoni</i> ,	Praziquantel 40 mg/kg/day in 2 doses for 1 day	
<i>S. haematobium</i>		
<i>S. japonicum</i> ,	Praziquantel 60 mg/kg/day in 3 doses for 1 day	
<i>S. mekongi</i>		
Strongyloidiasis	Ivermectin 200 mg/kg/day for 2 days. For 7 days if immunocompromised	Albendazole 400 mg q.d. for 3 days
Tapeworm intestinal infections	Praziquantel 5–10 mg/kg once	
Trichinellosis	Steriods for severe symp- toms plus Mebendazole 200–400 mg t.i.d. for 3 days, then 400–500 mg t.i.d. for 10 days	Albendazole 400 mg b.i.d. for 8–14 days
Trichuriasis (whipworm)	Mebendazole 100 mg b.i.d. or albendazole 400 mg q.d. for 3 days	Ivermectin 200 mg/kg/ day for 3 days

### *Amebiasis*

1. To eliminate intraluminal infection
  - Metronidazole 500–750 mg p.o. t.i.d. for 7–10 days
  - Tinidazole 2 g p.o. q.d. for 3 days
2. To eliminate intraluminal encysted organisms
  - Paromomycin – 25–30 mg/kg/day p.o. in three divided doses for 7 days
  - Iodoquinol – 650 mg p.o. t.i.d. daily for 20 days

### *Giardiasis*

- Metronidazole 250 mg p.o. t.i.d. for 5 days
- Tinadazole 2 g single dose

## PARASITIC INFESTATIONS

### *Angiostrongyliasis*

- Supportive and corticosteroids

### *Ascariasis*

- Treatment of choice: Mebendazole 100 mg b.i.d. for 3 days
- Alternative treatments: Pyrantel pamoate 11 mg/kg or albendazole 400 mg once

### *Cutaneous Larva Migrans*

- Treatment of choice: Ivermectin 200 mg/kg p.o. q.d. for 1–2 days
- Alternative treatments: Albendazole 400 mg p.o. q.d. for 3 days

### *Cysticercosis*

- Treatment of choice: Albendazole 400 mg p.o. b.i.d. for 8–30 days. Concurrent steroids for CNS disease
- Alternative treatments: Praziquantel 50–100 mg/kg/day p.o. in 3 doses for 30 days

### *Dracunculiasis*

- Metronidazole 250 mg t.i.d. for p.o. 10 days plus worm removal

### ***Echinococcosis/Hydatid Cyst***

- Treatment of choice: Perioperative albendazole followed by surgery
- Alternative treatments: Albendazole 400 mg p.o. b.i.d. for 1–6 months

### ***Enterobiasis/Pinworm***

- Pyrantel pamoate 11 mg/kg p.o. once
- Albendazole 400 mg p.o. once
- Mebendazole 100 mg p.o. once
- Repeat after 2 weeks

### ***Hook worm/Ancylostomiasis***

- Albendazole 400 mg p.o. once or
- Mebendazole 100 mg p.o. b.i.d. for 3 days or
- Pyrantel pamoate 11 mg/kg p.o. q.d. for 3 days

### ***Lymphatic Filariasis***

- Diethylcarbamazine 6 mg/kg p.o. once

### ***Loiasis***

- Diethylcarbamazine 6 mg/kg p.o. once

### ***Tropical Pulmonary Eosinophilia***

- Diethylcarbamazine 6 mg/kg/day p.o. in 3 doses for 12–21 days

### ***Trypanosoma Cruzi***

- Benznidazole for acute infection only

### ***Onchocerciasis***

- Ivermectin 150 mcg/kg p.o. once, repeat every 6–12 months

### ***Fluke Infections***

- Liver flukes, intestinal flukes: Praziquantel 75 mg/kg/day p.o. in 3 doses × 1 day
- Lung fluke: Praziquantel 75 mg/kg/day p.o. in 3 doses × 2 days
- Sheep liver fluke: Triclabendazole 10 mg/kg p.o. once

### ***Schistosomiasis***

- *S. mansoni*, *S. haematobium*: Praziquantel 40 mg/kg/day p.o. in 2 doses × 1 day
- *S. japonicum*, *S. mekongi*: Praziquantel 60 mg/kg/day p.o. in 3 doses × 1 day

### ***Strongyloidiasis***

- Treatment of choice: Ivermectin 200 mcg/kg p.o. q.d. × 2 days. For 7 days if immunocompromised
- Alternative treatments: Albendazole 400 mg p.o. q.d. × 3 days

### ***Tapeworm Intestinal Infections***

- Praziquantel 5–10 mg/kg p.o. once

### ***Trichinellosis***

- Treatment of choice: Steroids for severe symptoms plus mebendazole 200–400 mg p.o. t.i.d. × 3 days, then 400–500 mg p.o. t.i.d. × 10 days
- Alternative treatments: Albendazole 400 mg p.o. b.i.d. × 8–14 days

### ***Trichuriasis (Whipworm)***

- Treatment of choice: Mebendazole 100 mg p.o. b.i.d. × 3 days or albendazole 400 mg p.o. q.d. × 3 days
- Alternative treatments: Ivermectin 200 mg/kg p.o. q.d. × 3 days

### ***Albendazole***

Brand name: Albenza

Manufacturer: GlaxoSmithKline

Dosages:

- Ancylostomiasis and necatoriasis: 400 mg p.o. as a single dose
- Ascariasis: 400 mg p.o. as a single dose
- Clonorchiasis: 10 mg/kg p.o. daily for 7 days. Cutaneous larva migrans: 400 mg p.o. q.d. for 3 days
- Echinococcus granulosus infection, hydatid disease: 60 kg or greater, 400 mg p.o. twice daily for three 28-day cycles
- Enterobiasis: 400 mg p.o. as a single dose; repeat in 2 weeks
- Enterocolitis, eosinophilic – Infection by *Ancylostoma caninum*: 400 mg p.o. as a single dose
- Infection by *Gnathostoma*: 400 mg p.o. b.i.d. for 21 days

- Infection by *Microsporida*: Intestinal due to *E. intestinalis*, 400 mg p.o. twice daily for 21 days

Contraindications:

- Hypersensitivity to albendazole or benzimidazole products
- Pregnancy
- Impaired liver function

Adverse effects:

- Gastrointestinal: Abdominal pain, nausea, vomiting, hepatotoxicity
- Neurologic: Headache
- Renal: Acute renal failure (rare)
- Hematologic: Agranulocytosis, granulocytopenia, leukopenia, pancytopenia, thrombocytopenia (rare)

Drug interactions:

- Increased risk of albendazole toxicity with praziquantel and dexamethasone

Pregnancy: C

Lactation: Safe

Relative cost: \$\$\$

## ***Mebendazole***

Brand name: Vermox

Manufacturer: McNeil Consumer Health

Dosages:

- Ancylostomiasis and necatoriasis: 100 mg p.o. b.i.d. for 3 days
- Ascariasis: 100 mg p.o. b.i.d. for 3 days
- Enterobiasis: 100 mg p.o. one time dose
- Trichuriasis: 100 mg p.o. b.i.d. for 3 days

Treatment may be repeated in 3 weeks in all the above conditions.

Contraindications/cautions:

- Hypersensitivity to mebendazole products
- Caution in patients – 2 years
- Pregnancy

Adverse effects:

- Gastrointestinal: Abdominal pain, constipation, diarrhea, hepatitis
- Neurologic: Headache, seizure
- Dermatologic: Rash
- Drug interactions: No significant drug interactions

Pregnancy: C

Lactation: Safe

Relative cost: \$\$



### *Ivermectin*

Brand name:

Stromectol Manufacturer: Merck & Co., Inc.

Dosages:

- Infection by *Onchocerca volvulus*: 150 mcg/kg, p.o. single oral dose; retreatment interval between 3 and 12 months
- Intestinal strongyloidiasis: 200 mcg/kg, p.o. single oral dose

Contraindications/cautions:

- Hypersensitivity to ivermectin or components
- Pregnancy

Adverse effects:

- Gastrointestinal: Disease of GI tract, nausea, vomiting, diarrhea
- Neurologic: Dizziness, headache
- Dermatologic: Pruritus

Drug interactions: No significant drug interactions

Pregnancy: C

Lactation: Safety unknown

Relative cost: \$

### *Praziquantel*

Brand name: Biltricide

Manufacturer: Bayer

Indications:

- Schistosomiasis: 20 mg/kg p.o. t.i.d. once
- Clonorchiasis, Chinese liver fluke: 25 mg/kg p.o. t.i.d. once
- Tapeworms: 5–10 mg/kg p.o. once
- Intestinal flukes: 25 mg/kg p.o. t.i.d. once

Contraindications/cautions:

- Hypersensitivity to praziquantel
- Ocular cysticercosis

Adverse effects:

- Gastrointestinal: Abdominal pain
- Cardiovascular: Cardiac dysrhythmia, heart block
- Neurologic: Dizziness, headache, seizure
- Other: Malaise

Drug interactions:

- Chloroquine may decrease praziquantel levels
- Combination may increase albendazole levels

Pregnancy category: B

- Lactation: Avoid breast feeding for 3 days after last dose
- Relative cost: \$\$\$

### ***Thiabendazole***

Brand name: Mintezol

Manufacturer: Merck & Co., Inc.

Dosages:

- Ascariasis: (Not first line therapy): 50 mg/kg/day p.o. q. 12h. for 2 days
- Cutaneous larva migrans – for 2 days
- Visceral larva migrans – for 7 days
- Trichinosis – for 2–3 days
- Dracunculosis – for 3 days

Contraindications/cautions:

- Hypersensitivity to thiabendazole products
- Prophylactic treatment of pinworm infestation

Adverse effects:

- Gastrointestinal: Nausea, vomiting, anorexia, diarrhea, hepatotoxicity
- Neurologic: CNS finding, dizziness, drowsiness
- Dermatologic: Erythema multiforme, multiform, Stevens-Johnson syndrome

Drug interactions:

- Combination may increase theophylline levels and the risk of toxicity

Pregnancy category: C

Lactation: Safety unknown

Relative cost: \$

### ***Pyrantel Pamoate***

Brand name: Ascarel, Pamix, Pin-X

Manufacturer: Generic

Dosages:

- Enterobiasis: 11 mg/kg (up to maximum 1 g) p.o. once
- Ascariasis: 11 mg/kg (up to maximum 1 g) p.o. once

Contraindications/cautions:

- Hypersensitivity to drug
- Pregnancy
- Liver disease

Adverse effects:

- Gastrointestinal: Abdominal discomfort, nausea, vomiting
- Neurologic: Dizziness, headache, somnolence

Drug interactions: No major drug interactions

Pregnancy category: Generally regarded as unsafe

Lactation: Safety unknown

Relative cost: \$

### *Tinidazole*

Brand name: Tindamax

Manufacturer: Mission Pharmacal Company

Dosages:

- Intestinal amebiasis: 2,000 mg p.o. q.d. × 3 days
- Amebic liver abscess: 2,000 mg p.o. q.d. × 3–5 days
- Giardiasis: 2,000 mg p.o. × 1 day. Give with food

Contraindications/cautions:

- Hypersensitivity to drug or components
- Caution in impaired liver function
- Caution in disulfiram use, alcohol use, CNS disorder, blood dyscrasia

Adverse effects:

- Gastrointestinal: Candidiasis, nausea, vomiting
- Neurologic: Seizures, peripheral neuropathy
- Pulmonary: Bronchospasm
- Hematologic: Thrombocytopenia
- Dermatologic: Stevens-Johnson syndrome, erythema multiforme
- Other: Menorrhagia

Drug interactions:

- Disulfiram like reaction with disulfiram, lopinavir/ritonavir, tipronavir, diazoxide, ethanol
- May increase levels of lithium, phenytoin, cyclosporine, tacrolimus

Pregnancy: C

Lactation: Unsafe

Relative cost: \$

### *Paromomycin*

Brand name: Humatin

Manufacturer: King Pharmaceuticals, Inc.

## Dosages:

- Intestinal amebiasis: 25–35 mg/kg/day p.o. divided into 3 doses for 5–10 days
- Hepatic encephalopathy: 1,000 mg p.o. q.i.d. × 5–6 days
- Cryptosporidial diarrhea in HIV: 1,500–3,000 mg p.o. divided 3–6 times a day. Alternative – 1,000 mg p.o. b.i.d. × 12 weeks in combination with azithromycin 600 mg p.o. q.d. × 4 weeks. Give with food.

## Contraindications/cautions:

- Hypersensitivity to drug or components
- Caution in impaired renal function
- Caution in intestinal obstruction, inflammatory bowel disease, neurotoxic agents, ototoxic agents, dehydration, neuromuscular disease, auditory or vestibular dysfunction

## Adverse effects:

- Gastrointestinal: Enterocolitis, nausea, abdominal cramps, diarrhea
- Other: Nephrotoxicity, ototoxicity, neurotoxicity

## Drug interactions:

- Increased risk of nephrotoxicity with acyclovir, aminoglycoside, cyclosporine, flucytosine, foscarnet, gancyclovir, mitomycin, penicillamine, sirolimus, vancomycin

Pregnancy: C

Lactation: Probably safe

Relative cost: \$\$\$

## *Iodoquinol*

Brand name: Yodoxin

Manufacturer: Glenwood, LLC

## Dosage:

- Intestinal amebiasis: 650 mg p.o. t.i.d. × 20 days. Give after meals; repeat treatments should be performed in 2–3-week intervals

## Contraindications/cautions:

- Hypersensitivity to drug or components
- Hypersensitivity to iodine
- Caution in hepatic dysfunction
- Caution in thyroid disease

## Adverse effects:

- Gastrointestinal: Nausea, vomiting, abdominal pain
- Dermatologic: Pruritis, skin discoloration
- Other: Optic neuritis, peripheral neuropathy, headache

Drug interactions:

- Inadequate immunologic response to concomitant live oral typhoid vaccine
- May decrease levels of mycophenolate mofetil

Pregnancy: C

Lactation: Safety unknown

## INFECTIVE ENDOCARDITIS PROPHYLAXIS FOR GI PROCEDURES

The administration of prophylactic antibiotics solely to prevent endocarditis is not recommended for patients who undergo GI tract procedures, including diagnostic esophagogastroduodenoscopy or colonoscopy, as recommended by American Heart Association 2007 guidelines.

# 8

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## Hepatitis

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*Shilpa Madadi, MD  
and Shishir Mathur, MBBS*

### *CONTENTS*

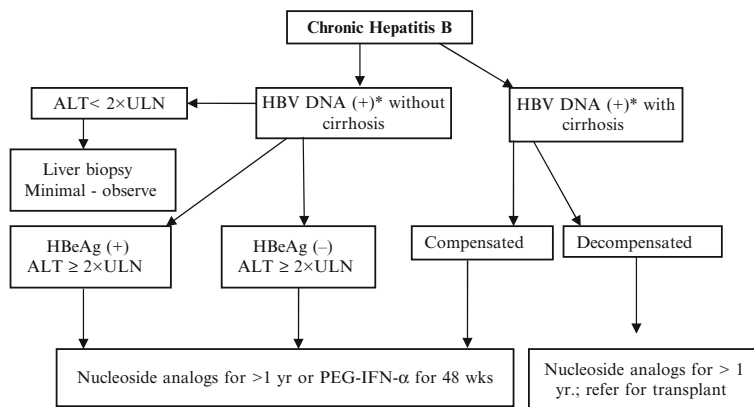
CHRONIC HEPATITIS B  
CHRONIC HEPATITIS C  
AUTOIMMUNE HEPATITIS  
WILSON'S DISEASE

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## CHRONIC HEPATITIS B

### *Hepatitis B Management*



ULN: Upper limit of normal

IFN- $\alpha$ : Interferon- $\alpha$

\* For HBeAg (-),  $\geq 2 \times 10^3$  IU/mL ( $\geq 4 \times 10^3$  copies/mL)

For HBeAg (+),  $\geq 2 \times 10^4$  IU/mL ( $\geq 4 \times 10^4$  copies/mL)

### Lamivudine

Trade name: Epivir HBV

Manufacturer: GlaxoSmithKline

Dosage: 100 mg p.o. q.d., currently not recommended as first-line monotherapy for HBV

Contraindications:

- Hypersensitivity to drug

Adverse effects:

- Gastrointestinal: Decrease in appetite, nausea and vomiting, pancreatitis, hepatomegaly, relapsing type B viral hepatitis
- Neurologic: Headache, fatigue
- Endocrine metabolic: Lactic acidosis, lipodystrophy

Pregnancy category: C

Relative cost: \$

### *Adefovir Dipivoxil*

Trade name: Hepsera

Manufacturer: Gilead Sciences

Dosage: Chronic hepatitis B – 10 mg p.o. q.d.

Contraindications:

- Hypersensitivity to drug

Adverse effects:

- Gastrointestinal: Abdominal pain, diarrhea, flatulence, indigestion, nausea
- Neurologic: Asthenia, headache, fatigue
- Dermatologic: Pruritus, rash

Pregnancy category: C

Relative cost: \$\$\$

### *Entecavir*

Trade name: Baraclude

Manufacturer: Bristol-Myers-Squibb

Dosage: Chronic hepatitis B

- Nucleoside-naïve: 0.5 mg p.o. q.d. 2h. before or after meal
- Lamivudine-resistant: 1 mg p.o. q.d.

Contraindications:

- Hypersensitivity to drug

Adverse effects:

- Gastrointestinal: Nausea, recurrent hepatitis
- Neurologic: Dizziness, headache, fatigue

Pregnancy category: C

Relative cost: \$\$\$\$

### *Telbivudine*

Trade Name: Tyzeka

Manufacturer: Idenix Pharmaceuticals, Inc./Novartis

Dosage: Chronic hepatitis B – 600 mg p.o. q.d.

Contraindications:

- Hypersensitivity to drug

Adverse effects:

- Gastrointestinal: Abdominal pain
- Neurologic: Headache, malaise, fatigue
- Respiratory: Nasopharyngitis, upper respiratory infection
- Musculoskeletal: Elevated creatine kinase level

Pregnancy category: B

Relative cost: \$\$



### *Tenofovir*

Trade name: Viread

Manufacturer: Gilead Pharmaceuticals, Inc.

Dosage: Chronic hepatitis B – 300 mg p.o. q.d.

Contraindications:

- Hypersensitivity to drug

Adverse effects:

- Gastrointestinal: Diarrhea, nausea, exacerbation of hepatitis with discontinuation
- Infections: Sinusitis
- Integument: Rash
- Metabolic: Lactic acidosis, worsening renal function
- Skeletal: Decreased bone density

Drug interactions:

- Truvada and Atripla contain tenofovir; didanosine, atazanovir, and lopinavir/ritonavir increase tenofovir concentrations. Coadministration with drugs that decrease renal function could increase tenofovir concentrations

Pregnancy category: B

Lactation: Possibly unsafe

Relative cost: \$\$

### *Pegylated Interferon $\alpha$ -2a*

Trade name: Pegasys

Manufacturer: Roche

Dosage:

- Chronic hepatitis B – 180 mcg weekly s.c. for 48 weeks

Contraindications:

- Hypersensitivity to drug
- Decompensated liver disease
- Significant preexisting psychiatric disease
- Autoimmune diseases
- Platelet count <70,000/mL

Adverse effects:

- Neurologic: Headache, insomnia, cerebral hemorrhage, peripheral neuropathy
- Hematologic: Anemia, aplastic anemia, neutropenia, thrombocytopenia, thrombotic thrombocytopenic purpura

- Immunologic: Autoimmune disease (rare)
- Musculoskeletal: Myalgia, myositis, fatigue, fever, influenza-like illness, rigor
- Dermatologic: Alopecia, injection site reaction, pruritus
- Psychiatric: Anxiety, irritability, aggressive behavior, depression, psychotic disorders, suicide

Pregnancy category: C

Relative cost: \$\$\$\$\$

### *Interferon $\alpha$ -2b*

Trade name: Intron

Manufacturer: Schering Corp.

Dosage:

- Patients with HBeAg positive chronic HBV (HBV DNA  $\geq 2 \times 10^4$  IU/mL) and ALT  $> 2 \times$  ULN or moderate/severe hepatitis upon liver biopsy, 5 mcg s.c. q.d. or 15 mcg s.c. 3 times/week (based on body weight) for 4 months
- Patients with HBeAg negative chronic HBV (HBV DNA  $\geq 2 \times 10^3$  IU/mL) and ALT  $> 2 \times$  ULN or moderate/severe hepatitis upon liver biopsy for 1 year

Contraindications:

- Hypersensitivity to drug
- Decompensated liver disease
- Significant preexisting psychiatric disease
- Autoimmune hepatitis. Platelet count  $< 70,000$ /mL

Adverse effects:

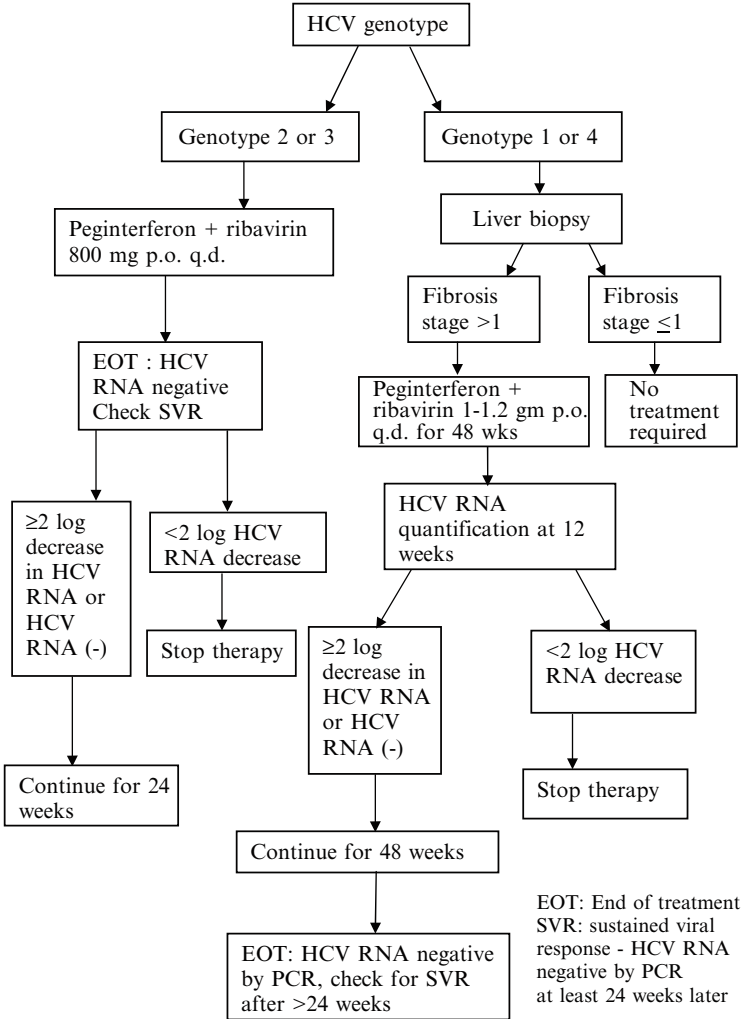
- Gastrointestinal: Colitis, pancreatitis
- Hematologic: Autoimmune thrombocytopenia, myelosuppression
- Dermatologic: Injection site reaction
- Ophthalmic: Disorders of the eyes
- Other: Influenza-like illness

Pregnancy category: C

Relative cost: \$\$\$\$\$

# CHRONIC HEPATITIS C

## *Hepatitis C Management*



## ***Pegylated Interferon $\alpha$ -2a***

Trade name: Pegasys

Manufacturer: Roche

Dosage:

- Genotypes 1, 4: 180 mcg s.c. weekly for 48 weeks in combination with ribavirin
- Genotypes 2, 3: 180 mcg s.c. weekly for 24 weeks in combination with ribavirin

Contraindications:

- Hypersensitivity to drug
- Decompensated liver disease
- Significant preexisting psychiatric disease
- Autoimmune diseases
- Platelet count  $<70,000/\text{mL}$

Adverse effects:

- Neurologic: Headache, insomnia, cerebral hemorrhage, peripheral neuropathy
- Hematologic: Anemia, aplastic anemia, neutropenia, thrombocytopenia, thrombotic thrombocytopenic purpura
- Immunologic: Autoimmune disease (rare)
- Musculoskeletal: Myalgia, myositis, fatigue, fever, influenza-like illness, rigor
- Dermatologic: Alopecia, injection site reaction, pruritus
- Psychiatric: Anxiety, irritability, aggressive behavior, depression, psychotic disorders, suicide

Pregnancy category: C

Relative cost: \$\$\$\$\$

### ***Dosage Adjustments for PEG-Interferon $\alpha$ -2a (Pegasys)***

#### **Depression**

*For mild depression:* No dosage change necessary

*For moderate depression:* Decrease dose to 135 mcg s.c. q.1week; if necessary, decrease to 90 mcg. If symptoms improve or remain stable for  $\geq 4$  weeks, continue reduced dosing or return to normal dose

*For severe depression:* Discontinue treatment immediately and permanently; obtain immediate psychiatric consultation

#### **Hematological**

*For neutrophil count  $<750/\text{mm}^3$ :* Decrease dose to 135 mcg s.c. q.1week

*For neutrophil count  $<500/mm^3$* : Suspend treatment until neutrophil count  $>1,000/mm^3$ ; reinstitute at 90 mcg s.c. q.1week

*For platelet count  $<50,000/mm^3$* : Decrease dose to 90 mcg s.c. q.1week

*For platelet count  $<25,000/mm^3$* : Discontinue treatment

### Hepatic Impairment

Decompensated hepatic disease (e.g., Child-Pugh class B or C) should not be treated with PEG-interferon  $\alpha$ -2a

Progressive ALT increases above baseline, decrease the dose to 135 mcg s.c. q.1week, resume after resolution of ALT flare. Therapy discontinuation considered with persistent ALT elevations  $>10$  times the upper limit

### Renal Impairment

CrCl  $\geq 50$  mL/min: No dosage adjustment needed

CrCl  $< 50$  mL/min: Accumulation of PEG-interferon  $\alpha$ -2a may occur; close monitoring for adverse reactions requiring dosage reduction is recommended

### Intermittent Hemodialysis

135 s.c. q.1week. Monitor patients closely

### *Pegylated Interferon $\alpha$ -2b*

Trade name: PEG-Intron

Manufacturer: Schering Corp.

Dosage:

- Genotypes 1, 4: 1.5 mcg/kg/week s.c. for 48 weeks in combination with ribavirin
- Genotypes 2, 3: 1.5 mcg/kg/week s.c. for 24 weeks in combination with ribavirin

Body weight (kg)	PEG-intron vial strength	PEG-intron (mcg) to administer
<40	50 mcg/0.5 mL	50
40–50	80 mcg/0.5 mL	64
51–60		80
61–75	120 mcg/0.5 mL	96
76–85		120
>95	150 mcg/0.5 mL	150

Contraindications:

- Hypersensitivity to drug
- Decompensated liver disease

- Significant preexisting psychiatric disease
- Autoimmune diseases
- Platelet count  $<70,000/\text{mL}$

Adverse effects:

- Gastrointestinal: Colitis, pancreatitis
- Hematologic: Autoimmune thrombocytopenia, myelosuppression
- Dermatologic: Injection site reaction
- Ophthalmic: Disorders of retina
- Other: Influenza-like illness

Pregnancy category: C

Relative cost: \$\$\$\$

## ***Dosage Adjustments for PEG-Interferon $\alpha$ -2b***

### **Depression**

*Mild depression:* No change

*Moderate depression:* Decrease dose by 50%. If condition remains stable, continue reduced dosage. If symptoms improve and are stable for  $\geq 4$  weeks, continue reduced dosage regimen or return to normal dose

*Severe depression:* Discontinue PEG-interferon  $\alpha$ -2b permanently

*White blood cell count  $<1,500/\text{mm}^3$ , neutrophil count  $<750/\text{mm}^3$  or platelet count  $<80,000/\text{mm}^3$ :* Decrease dose by 50%

*Hemoglobin  $<8.5$  g/dL, white blood cell count  $<1,000/\text{mm}^3$ , neutrophil count  $<500/\text{mm}^3$  or platelet count  $<50,000/\text{mm}^3$ :* Permanently discontinue therapy

### **Maximum Dosage Limits**

*Adults:* 1 mcg/kg

*Elderly:* 1mcg/kg s.c. q.1week for monotherapy or 1.5mcg/kg s.c. q.1week in combination with ribavirin

*Adolescents:* Safe and effective use has not been established

*Children:* Safe and effective use has not been established

### **Hepatic Impairment**

Decompensated hepatic disease (e.g., active alcoholism, ascites, coagulopathy, hypoalbuminemia, or jaundice) should not be treated with PEG-interferon  $\alpha$ -2b

### **Renal Impairment**

If renal function decreases during treatment, discontinue

CrCl  $>50$  mL/min: No dosage adjustment needed

CrCl 30–50 mL/min: Reduce dose by 25%

CrCl 10–29 mL/min: Reduce dose by 50%

### **Intermittent Hemodialysis**

Reduce dose by 50%

### ***Ribavirin***

Trade name: Copegus, Rebetol

Manufacturer: Copegus (Roche)

Dosage in combination with PEG-interferons:

- Genotype 1, 4:
  - ≤75 kg: 1,000 mg/day, p.o. in two divided doses for 48 weeks
  - >75 kg: 1,200 mg/day, p.o. in two divided doses for 48 weeks
- Genotype 2, 3: 800 mg/day, p.o. in two divided doses, for 24 weeks
- Coinfection with HIV: 800 mg/day p.o. in two divided doses for 48 weeks

Contraindications:

- Hypersensitivity to drug
- Cardiac disease, significant or unstable; potential worsening due to drug-induced anemia
- Pregnancy or pregnant partner of male patient; may cause birth defects and/or death of the exposed fetus
- Hemoglobinopathy (such as thalassemia major and sickle-cell anemia)
- Decompensated liver disease
- Autoimmune diseases
- Renal function impairment

Adverse effects:

- Gastrointestinal: Abdominal pain, nausea, vomiting, pancreatitis
- Hematologic: Hemolytic anemia, cardiac and pulmonary events, thrombotic thrombocytopenic purpura (less than 1%)
- Dermatologic: Pruritus, rash

Pregnancy category: X

Relative cost: \$

### ***Ribavirin Dosage Adjustments***

*No cardiac history and hemoglobin <10 g/dL:* Decrease dose to 600 mg p.o. q.d. (200 mg p.o. q.a.m. and 400 mg p.o. q.p.m.)

*No cardiac history and hemoglobin <8.5 g/dL:* Permanently discontinue ribavirin therapy

*History of cardiovascular disease with hemoglobin decreases by  $\geq 2$  g/dL during any 4-week period:* Decrease ribavirin dose to 600 mg s.c. q.d. If the hemoglobin remains  $< 12$  g/dL after 4 weeks on the reduced dose, discontinue ribavirin therapy

### ***Maximum Dosage Limits***

Adults

#### **Hepatic Impairment**

No specific guidelines are available

#### **Patients with Renal Impairment:**

CrCl  $\geq 50$  mL/min

Closely monitor older patients ( $> 50$  years of age) for development of anemia, especially if renal function impairment coexists

CrCl  $< 50$  mL/min: Oral ribavirin therapy should not be given

### ***Interferon $\alpha$ -2b***

Trade name: Intron

Manufacturer: Schering Corp.

Dosage:

- Genotypes 1, 4: Monotherapy – 3 million IU s.c. three times/week for 1 year
- Genotypes 2, 3: Monotherapy – 3 million IU s.c. three times/week for 6 months
- Combination therapy: Ribavirin:
  - $\leq 75$  kg: 1,000 mg/day, in two divided doses for duration of interferon therapy
  - $> 75$  kg: 1,200 mg/day, in two divided doses for duration of interferon therapy

Contraindications:

- See HBV section

Adverse effects:

- See HBV section

Pregnancy category: C

Relative cost: \$\$\$\$



### ***Interferon $\alpha$ -2a***

Trade name: Roferon A

Manufacturer: Roche

Dosage:

- Monotherapy:
  - Genotypes 1 and 4: 3 million IU administered s.c. three times/week for 1 year
  - Genotypes 2 and 3: 3 million IU administered s.c. three times/week for 6 months
- Combination therapy: Ribavirin:
  - $\leq 75$  kg: 1,000 mg/day, in two divided doses for duration of interferon therapy
  - $>75$  kg: 1,200 mg/day, in two divided doses for duration of interferon therapy

Contraindications:

- See HBV section

Adverse effects:

- See HBV section

Pregnancy category: C

Relative cost: \$\$\$\$\$

### ***Consensus Interferon (Interferon Alfacon-1)***

Trade name: Infergen

Manufacturer: Amgen/Three Rivers, Inc.

Dosage:

- 9 mcg s.c. 3 times/week for 6 months; 15 mcg s.c. 3 times/week for 48 weeks for relapsers, nonresponders (to 9 mcg)

Contraindications:

- See HBV section for interferons

Adverse effects:

- See HBV section for interferons

Pregnancy category: C

Relative cost: \$\$\$\$\$

## **AUTOIMMUNE HEPATITIS**

### ***Azathioprine***

Please see Chap. 5 for drug information

### ***Autoimmune Hepatitis***

Please see Chap. 5 for drug information

#### ***Prednisone***

Please see Chap. 5 for drug information

#### ***6-Mercaptopurine***

Trade name: Purinethol

Manufacturer: Gate Pharmaceuticals

Dosage:

- 75–125 mg p.o. q.d. as second line agent in steroid plus azathioprine refractory cases

Contraindications:

- Hypersensitivity to drug/class/component
- Impaired renal function

Adverse Reactions:

- Gastrointestinal: Nausea, vomiting, diarrhea, hepatotoxicity, GI ulceration, pancreatitis, jaundice, abdominal pain
- Renal: Urate nephropathy, nephrolithiasis
- Hematological: Anemia, leukopenia, thrombocytopenia, tumor lysis syndrome, immunosuppression
- Endocrine: Hyperuricemia
- Dermatological: Oral lesions
- Others: Anorexia, malaise, fever

Pregnancy category: D

Relative cost: \$

### **WILSON'S DISEASE**

#### ***Penicillamine***

Trade name: Cuprimine

Manufacturer: Aton Pharma, Inc.

Dosage: 750–1,500 mg/day p.o. in divided doses t.i.d. to q.i.d.

Contraindications:

- Hypersensitivity to drug/class/component
- Pregnancy
- Breastfeeding
- History of penicillamine related aplastic anemia or agranulocytosis

- Renal impairment
- Hypersensitivity to penicillin

Adverse Reactions:

- Gastrointestinal: Nausea, vomiting, epigastric pain, hepatic failure, intrahepatic cholestasis (rare), hepatitis (rare), pancreatitis
- Neurological: Myasthenia gravis
- Renal: Nephrotic syndrome, renal failure
- Hematological: Aplastic anemia, leukopenia, agranulocytosis, thrombocytopenia
- Immunological: Hypersensitivity reaction, SLE
- Dermatological: Exfoliative dermatitis, toxic epidermal necrolysis (rare), pemphigus

Pregnancy category: D

Relative cost: \$\$

### *Trientine*

Trade Name: Syprine

Manufacturer: Merck & Co., Inc.

Dosage: 250–500 mg p.o. q.i.d., maximum 2 g/day

Contraindications:

- Hypersensitivity to drug/class/component
- Rheumatoid arthritis
- Biliary cirrhosis
- Cystinuria

Adverse effects:

- Hematological: Iron deficiency anemia
- Immunological: Lupus, contact dermatitis

Pregnancy category: C

Relative cost: \$\$\$

### *Zinc Sulfate*

Trade Names: Orazinc, Zincate

Manufacturer: Mericon Industries Inc.

Dosage: 50 mg elemental zinc p.o. t.i.d.

Adverse reactions:

- Gastrointestinal: Nausea, stomach upset, heartburn
- Immunological: May have immunosuppressant effects

Pregnancy category: C

Relative cost: \$

# 9

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## Cholestasis

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*Shishir Mathur, MBBS*

### CONTENTS

PRIMARY BILIARY CIRRHOSIS

PRIMARY SCLEROSING CHOLANGITIS

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### PRIMARY BILIARY CIRRHOSIS

#### *Ursodiol*

Trade name: URSO Forte, Actigall

Manufacturer: Generic; URSO Forte – Axcan Pharma; Actigall – Watson Pharmaceuticals

Dosage:

- Primary biliary cirrhosis. Use 13–15 mg/kg p.o. q.d.
- Primary sclerosing cholangitis. Use 20–30 mg/kg p.o. q.d.
- Autoimmune hepatitis: Use with the initial therapy to induce remission as well as during continuation phase. Use 10 mg/kg p.o. q.d.

Contraindications/cautions:

- Hypersensitivity to drug or bile acids
- Gallstones: Calcified cholesterol, radiopaque stones, radiolucent bile pigment stones
- Unremitting acute cholecystitis
- Acute cholangitis
- Biliary obstruction

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Adverse effects:

- Gastrointestinal: Diarrhea, nausea, vomiting
- Musculoskeletal: Backache

Drug interactions:

- Concomitant fibric acid derivatives, oral contraceptives, bile acid binding resins, and antacids may decrease ursodiol efficacy

Pregnancy category: B

Lactation: Safety unknown

Relative cost: \$\$

## PRIMARY SCLEROSING CHOLANGITIS

### *UDCA*

See above

# 10

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## Hepatic Encephalopathy

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*Shilpa Madadi, MD  
and Shishir Mathur, MBBS*

### CONTENTS

LACTULOSE  
NEOMYCIN  
RIFAXIMIN

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### LACTULOSE

Brand name: Cephulac, Cholac, Constulose

Class: Nonabsorbed disaccharides

Manufacturer: Generic

Dosages:

- Treatment and prophylaxis of hepatic encephalopathy: Start with 30–45 ml (20 gm/30 ml) p.o. 3–4 times daily, then adjusted to achieve 2–3 soft formed stools/day or 300 ml (200 g) mixed with 700 ml of water or saline rectally as a retention enema (retain for 30–60 min) every 4–6 h. as needed
- Constipation: 15–30 ml p.o. once or twice daily

Contraindications/cautions:

- Hypersensitivity to lactulose products
- Galactosemia

Adverse effects:

- Gastrointestinal: Bloating, diarrhea, epigastric pain, flatulence, nausea, vomiting, cramps
- Endocrine metabolic: Hypernatremia, hypokalemia

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Drug interactions:

- Increases anticoagulation effects of coumadin

Pregnancy category: B

Lactation: Safety unknown

Relative cost: \$\$

## NEOMYCIN

Brand name: Neo-Fradin

Class: Nonabsorbed antibiotics

Manufacturer: Generic

Dosages:

- Hepatic encephalopathy: 4–12 g/day p.o. in divided doses for 5–6 days, maximum 12 g/day; do not use longer than 2 weeks

Contraindications/cautions:

- Hypersensitivity to neomycin/aminoglycosides
- Inflammatory/ulcerative gastrointestinal disease
- Intestinal obstruction

Adverse effects:

- Gastrointestinal: Diarrhea, nausea, vomiting
- Neurologic: Neuromuscular blockade finding
- Respiratory: Respiratory tract paralysis, concomitant anesthesia, muscle relaxants
- Renal: Nephrotoxicity
- Otic: Ototoxicity

Pregnancy category: D

Lactation: Safety unknown

Relative cost: \$\$\$

## RIFAXIMIN

Brand name: Xifaxan

Class: Nonabsorbed antibiotics

Manufacturer: Salix Pharmaceuticals

Dosage:

- Hepatic encephalopathy: 400 mg p.o. t.i.d.
- Small intestinal bacterial overgrowth: 400 mg p.o. t.i.d. for 2 weeks. Therapy may be repeated if required

## Contraindications/cautions:

- Hypersensitivity to rifaximin

## Adverse effects:

- Gastrointestinal: Constipation, vomiting, abdominal pain
- Neurologic: Headache
- Immunologic: Immune hypersensitivity reaction

Pregnancy category: C

Lactation: Safety unknown

Relative cost: \$\$



# 11

## Pruritis

*Marcy Coash, MD*

<i>Drug</i>	<i>Regimen (p.o.)</i>	<i>Efficacy</i>	<i>Adverse Effects</i>
<i>Antihistamines</i>	25–50 mg q.i.d.	Rarely provide significant relief apart from sedation	Drowsiness
Diphenhydramine			
Hydroxyzine	25 mg t.i.d.		
Cholestyramine	4–6 g 30 min before meals (or doses may be taken before and after breakfast without an evening dose)	Beneficial in most patients	Fat malabsorption, decreased absorption of other medications, constipation
Rifampin	300 mg b.i.d.	Beneficial in some, but not all controlled trials to date	Inducer of hepatic drug metabolizing enzymes, potential hepatotoxicity, red-orange discoloration of urine and secretions

(continued)

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<i>Drug</i>	<i>Regimen (p.o.)</i>	<i>Efficacy</i>	<i>Adverse Effects</i>
Ursodeoxycholic acid	13–15 mg/kg q.d. (higher in primary sclerosing cholangitis)	Beneficial in intrahepatic cholestasis of pregnancy	No major toxicity reported
Naltrexone	50 mg q.d.	Beneficial in small controlled trials	Opiate withdrawal symptoms, rare hepatotoxicity

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# 12

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## Nutrition and Enzyme Deficiency

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*Shishir Mathur, MBBS*

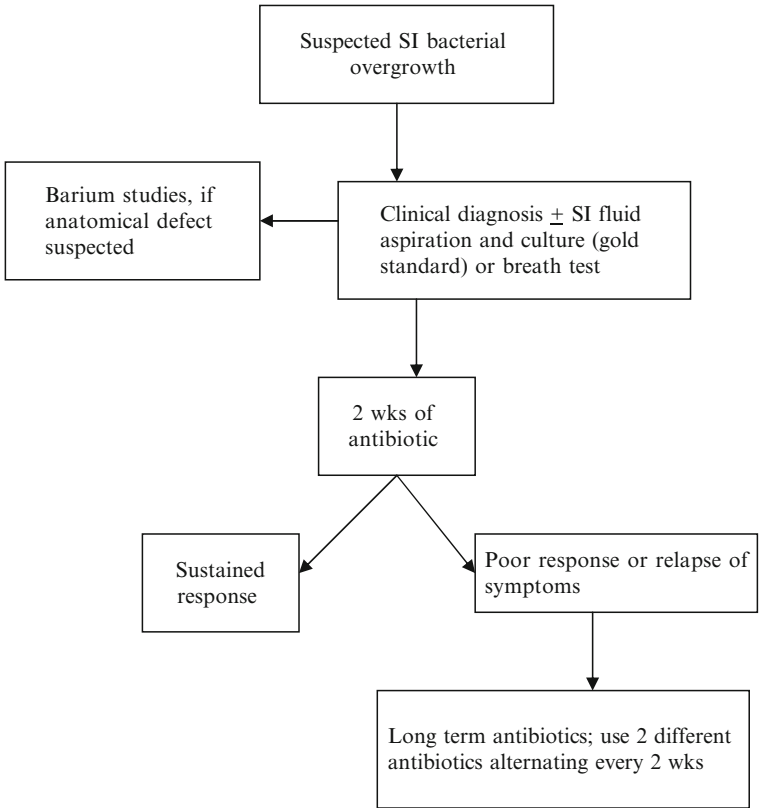
### *CONTENTS*

SMALL INTESTINAL (SI) BACTERIAL  
OVERGROWTH  
PANCREATIC INSUFFICIENCY  
LACTASE DEFICIENCY  
VITAMIN B12 DEFICIENCY/PERNICIOUS  
ANEMIA

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## SMALL INTESTINAL (SI) BACTERIAL OVERGROWTH



### *Amoxicillin – Clavulinic Acid*

Brandname: Augmentin

Class: Penicillin

Manufacturer: GlaxoSmithkline

Dosage:

- 500–875 mg p.o. b.i.d. or 250–500 mg p.o. t.i.d., usually for 2 weeks rotating with another antibiotic for 2 weeks

## Contraindications/cautions:

- Hypersensitivity to drug or class
- Hepatic dysfunction or cholestatic jaundice with augmentin
- Impaired liver function

## Adverse reactions:

- Gastrointestinal: Cholestatic jaundice, hepatotoxicity, diarrhea, pseudomembranous colitis
- Neurological: Seizures
- Renal: Interstitial nephritis
- Hematological: Anemia, leukopenia, thrombocytopenia
- Immunological: Hypersensitivity reaction, angioedema
- Dermatological: Rash, urticaria, contact dermatitis, erythema multiforme

## Drug interactions:

- Avoid concomitant live oral typhoid vaccine because of inadequate vaccine response
- May increase methotrexate levels

Pregnancy category: B

Lactation: Probably safe

Relative cost: \$\$\$

### ***Ciprofloxacin***

Please see Chap. 7 for drug details.

### ***Metronidazole***

Please see Chap. 6 for drug details.

### ***Rifaximin***

Please see Chap. 10 for drug details.

### ***Octreotide***

Please see Chap. 2 for drug details.

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**PANCREATIC INSUFFICIENCY**


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	<i>Lipase Content (USP Units)</i>	<i>Minimum Dose per Meal Needed to Treat Steatorrhea</i>
<i>Nonenteric coated preparations</i>		
Viokase 8	8,000	6 tablets
Viokase 16	16,000	3 tablets
Ilozyme	11,000	4 tablets
Generic pancrelipase	8,000	6 tablets
<i>Enteric coated preparations</i>		
Creon 5	5,000	9 caplets
Creon 10	10,000	5 caplets
Creon 20	20,000	2 caplets
Pancrease MT 4	4,000	11 tablets
Pancrease MT 10	10,000	4 tablets
Pancrease MT 16	16,000	3 tablets
Pancrease MT 20	20,000	2 tablets
Ultrase MT 5	5,000	10 tablets
Ultrase MT 12	12,000	4 tablets
Ultrase MT 18	18,000	3 tablets
Ultrase MT 20	20,000	2 tablets
Ku-Zyme HP	8,000	6 caplets
Zymase	12,000	4 caplets
Cotazyme-S	5,000	9 caplets

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### ***Pancrelipase***

Brand names: Cotazym, Cotazym-S, Creon 5, Creon 10, Creon 20, Ilozyme, Ku-Zyme, Pancrease, Pancrease MT 10, Pancrease MT 16, Pancrease MT 20, Pancrease MT 4, Pancron D/R, Ultrase, Ultrase MT 12, Ultrase MT 18, Ultrase MT 20, Viokase, Zymase

Manufacturers: Axcan Pharma, Solvay Pharmaceuticals Inc., McNeil-PPC, Inc., Schwarz Pharma

Class: Digestive enzymes with varying amounts of lipase, amylase, and protease

## Dosage:

- Refer to table for dosage. Titrate dosing to response; take with meals. (Do not cut/crush/chew. May open caps and sprinkle on soft food with pH < 5.5)

## Contraindications:

- Hypersensitivity to product or class
- Acute pancreatitis
- History of recurrent bowel obstruction, meconium ileus, Crohn's disease, short bowel syndrome or prior intestinal surgery

## Adverse reactions:

- Gastrointestinal: Fibrosing colonopathy, bowel obstruction, nausea, vomiting, bloating, cramps, diarrhea, constipation
- Immunological: Allergic reaction, hypersensitivity reaction

## Drug interactions:

- H2 blockers, proton pump inhibitors, antacids may cause premature dissolution of enteric-coated digestive enzyme products resulting in increased or decreased efficacy
- Concomitant use of oral iron may decrease iron absorption

Pregnancy category: C

Lactation: Safety unknown

Relativecost: \$\$\$

## LACTASE DEFICIENCY

### *Lactase*

Brand name: Lactaid

Manufacturer: Generic

## Dosage:

- Swallow or chew 3 caplets (original strength), 2 caplets (extra strength), or 1 caplet (ultra) with first bite of dairy product. Adjust dose based on response

Adverse reactions: No significant adverse effects or drug interactions

Pregnancy: Probably safe in pregnancy and lactation

Relative cost: \$

## VITAMIN B 12 DEFICIENCY/PERNICIOUS ANEMIA

### *Vitamin B 12 (Cyanocobalamin)*

## Dosage:

- Start 1,000 mcg s.c./i.m. q.d. × 1 week, then *q* week × 1 month, then *q* month for maintenance

- Poor oral absorption, but 1,000–2,000 mcg p.o. may be used for maintenance; also may be given intranasally

Contraindications/caution:

- Hypersensitivity to drug, class, or cobalt
- Hereditary optic atrophy
- Caution if uremia, myelosuppression, or folic acid deficiency

Adverse reactions:

- Gastrointestinal: Diarrhea, nausea
- Neurological: Ataxia, nervousness, headache
- Cardiovascular: Pulmonary edema, peripheral vascular thrombosis
- Renal: Hypokalemia
- Hematological: Thrombocytosis

Drug interactions:

- Impaired absorption of oral form with chloramphenicol, neomycin, H<sub>2</sub> antagonists, omeprazole, and colchicine

Pregnancy category: C

Lactation: Safe

Relative cost: \$



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## References

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3. Lok AS, McMahon BJ; AASLD (American Association for the Study of Liver diseases). Hepatology 2007; 45(2): 507–539
4. Prevention of infective endocarditis. Circulation 2007; 116(15): 1736–1754
5. Tarascon Pocket Pharmacopoeia 2006. Forest Pharmaceuticals, Inc.
6. Up To Date 2008

### RELATIVE COST

Cost codes used are for “per month” of maintenance therapy or “per course” of short-term therapy (e.g., antibiotics). Codes are calculated using average wholesale prices for the most common indication and route of each drug at a typical adult dosage. For maintenance therapy, costs are calculated based upon a 30-day supply or the quantity that might typically be used in a given month. When multiple forms are available, these codes reflect the least expensive generally available product. These codes should be used as a rough guideline only. Check with your local pharmacy if you have any questions.

<i>Code</i>	<i>Cost</i>
\$	<\$25
\$\$	\$25–49
\$\$\$	\$50–99
\$\$\$\$	\$100–199
\$\$\$\$\$	≥\$200

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# INDEX

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## A

- Achalasia, diffuse esophageal spasm
  - botulinum toxin, 32–33
  - nifedipine, 31–32
- Adalimumab, 49
- Adefovir dipivoxil, 84–86
- Albendazole, 72–78
- Alosetron, 24
- Amitriptyline, 21–22
- Amoxicillin–clavulanic acid,
  - 108–109
- Antihistamines, 105
- Autoimmune hepatitis
  - 6-mercaptopurine, 97
  - azathioprine, 42–45
- Azithromycin, 61–62, 64, 81

## B

- Balsalazide, 42–43, 45
- Biliary cirrhosis, 99–100
- Bisacodyl, 29

## C

- Carafate, 9–10
- Caspofungin, 66, 68–69
- Castor oil, 29–30
- Cefotaxime, 51–52
- Ceftriaxone, 52–53
- Cholangitis, 50
- Cholestasis, 99–100
- Cholestyramine, 60, 105
- Ciprofloxacin, 54–55, 109
- Clarithromycin, 10–11
- Clostridium difficile, 58
- Clotrimazole, 66–67
- Colestipol, 61
- Crohn's disease (CD), 40, 41, 43–46
- Cyclosporine, 45–46
- Cytomegalovirus (CMV), 70–72

## D

- Diarrhea, 22–23
- Dicyclomine hydrochloride, 19–20
- Diffuse esophageal spasm (DES)
  - botulinum toxin, 32–33
  - nifedipine, 31–32
- Diphenoxylate hydrochloride/
  - atropine sulfate, 22–23
- Diverticulitis, 50
- Docusate, 26
- Doxycycline, 62–65

## E

- Entecavir, 87
- Erythromycin, 33
- Esomeprazole, 13

## F

- Famotidine, histamine H2
  - antagonists, 8
- Fluconazole, 66–68
- Foscarnet, 70–72, 81

## G

- Ganciclovir, 70–71
- Gastroesophageal reflux disorder (GERD), 4
- Gastrointestinal bleeding
  - acute hemorrhage, esophageal
    - varices
      - nadolol, 18
      - nitroglycerin, 16–17
      - octreotide acetate, 14–15
      - propranolol, 17–18
      - vasopressin, 15–16
  - acute non-variceal upper,
    - esomeprazole, 13
    - pantoprazole sodium, 13
- Glucocorticoids, 43–44

**H**

## Hepatic encephalopathy

lactulose, 101–102

neomycin, 102

rifaximin, 102–103

## Hepatitis

adefovir dipivoxil, 86

autoimmune

6-mercaptopurine, 97

azathioprine, 42–45

chronic hepatitis B

adefovir dipivoxil, 86–87

entecavir, 87

lamivudine, 86

pegylated interferon  $\alpha$ -2a,

88–89

pegylated interferon  $\alpha$ -2b, 89

telbivudine, 97

tenofovir, 88

chronic hepatitis C

PEG-interferon  $\alpha$ 2a, 91–92, 95PEG-interferon  $\alpha$ 2b, 92–94, 96

ribavirin, 94–95

Wilson's disease

penicillamine, 97–98

trientine, 98

zinc sulfate, 98

## Hyoscyamine sulfate, 20–21

**I**

## Imipramine, 21

## Inflammatory bowel disease

Crohn's disease

6-mercaptopurine, 43–44

adalimumab, 47

azathioprine, 42–45

glucocorticoids, 43–44

infliximab, 40, 46–47

mesalamine, 41–42

ulcerative colitis

6-mercaptopurine, 43–44

azathioprine, 42–45

balsalazide, 42–43, 45

cyclosporine, 45–46

glucocorticoids, 43–44

infliximab, 40, 46–47

mesalamine, 41–42

mild management, 40

olsalazine, 42

sulfasalazine, 41, 42, 46

Infliximab, 40, 46, 89

Iodoquinol, 74, 81–82

Irritable bowel syndrome, 19–22

Ivermectin, 72, 76, 78

**L**

Lactase, 111

Lactulose, 28–29, 101–102

Lamivudine, 86–87

Lansoprazole, proton pump

inhibitors, 6

Levofloxacin, 53

Loperamide, 23, 34

Lubiprostone, 24–25

**M**

Magnesium citrate, 26–27

Mebendazole, 72–77

Mesalamine, 41–42

Methylcellulose, 25–26

Metoclopramide, 33–34

Metronidazole, 59, 72, 74, 108

Microbial infections,

gastrointestinal

bacterial infections

azithromycin, 62

*Campylobacter*, 62

cholestyramine, 60

*Clostridium difficile*, 58

colestipol, 61

doxycycline, 64–65

metronidazole, 59

*Salmonella*, 61–62*shigella* and *E. Coli*

gastroenteritis, 61

tetracycline, 65–66

vancomycin, 59–60

*vibrio cholerae* and *yersinia*

gastroenteritis, 62

Whipple's disease and *Listeria**monocytogenes*, 63

fungal infections

candidiasis, oropharyngeal

and esophageal, 66

caspofungin, 68–69

fluconazole, 67–68

nitazoxanide, 69

voriconazole, 68

infective endocarditis

prophylaxis, 82

- parasitic infestations, 74–76
  - albendazole, 76–77
  - iodoquinol, 81–82
  - ivermectin, 78
  - mebendazole, 77
  - paromomycin, 80–81
  - praziquantel, 78–79
  - pyrantel pamoate, 79–80
  - thiabendazole, 79
  - tinidazole, 80
- protozoal infections
  - amebiasis and giardiasis, 74
  - anthelmintic therapies, 72–73
- viral infections
  - CMV gastrointestinal disease, 70
  - foscarnet, 71–72
  - ganciclovir, 70–71
  - herpes simplex esophagitis, 70
  - valgancyclovir, 71
- Mineral oil, 27–28
- Motility disorders, gastrointestinal
  - constipation
    - bisacodyl, 29
    - castor oil, 29–30
    - docusate, 26
    - lactulose, 28–29
    - magnesium citrate, 26–27
    - methylcellulose, 25–26
    - mineral oil, 27–28
    - polyethylene glycol solution, 28
    - psyllium, 25
    - senna, 28–29
  - diffuse esophageal spasm (DES)
    - botulinum toxin, 32–33
    - nifedipine, 31–32
  - dumping syndrome, 34
  - gastroparesis
    - erythromycin, 33
    - metoclopramide, 33–34
  - irritable bowel syndrome
    - alosetron, 24
    - amitriptyline, 21–22
    - dicyclomine hydrochloride, 19–20
    - diphenoxylate hydrochloride/atropine sulfate, 22–23
    - hyoscyamine sulfate, 20–21
    - imipramine, 21
    - lubiprostone, 24–25
    - rapid transit dysmotility, 35
- N**
  - Nadolol, 18
  - Naltrexone, 105
  - Neomycin, 102
  - Nifedipine, 31–32
  - Nitazoxanide, 69
  - Nitroglycerin, 15–17
  - Norfloxacin, 53–54
  - Nutrition and enzyme deficiency
    - lactase deficiency, 111
    - pancreatic insufficiency, 110
    - small intestinal (SI) bacterial overgrowth
      - amoxicillin–clavulinic acid, 108–109
      - ciprofloxacin, 54–55, 109
      - metronidazole, 59, 72, 74, 109
      - octreotide, 30, 32, 109
      - rifaximin, 102–103, 109
      - vitamin B 12 deficiency/ pernicious anemia, 111–112
- O**
  - Octreotide, 30, 32, 109
  - Olsalazine, 42
  - Omeprazole, proton pump inhibitor, 4–8
- P**
  - Pancrelipase, 110–111
  - Pantoprazole sodium, 13
  - Paromomycin, 74, 80–81
  - Peptic disorders
    - amoxicillin, 10–11
    - carafate, 9–10
    - clarithromycin, 10–11
    - Helicobacter pylori*, 10
    - histamine H2 antagonists
      - famotidine, 8
      - ranitidine hydrochloride, 9
    - metronidazole, 10–11
    - proton pump inhibitors
      - esomeprazole magnesium (oral), 5–6

Peptic disorders (*Continued*)

- lansoprazole, 6
- omeprazole, 4–5
- pantoprazole sodium oral  
and IV, 6–7
- rabeprazole sodium, 7–8

## Peptic ulcer disease, 4

## Pernicious anemia, 111–112

## Polyethylene glycol solution, 28

## Praziquantel, 72–78

## Propranolol, 17

## Pruritis, 105–106

## Psyllium, 25

PUD. *See* Peptic ulcer disease

## Pyrantel pamoate, 72–75, 79–80

**R**

## Rabeprazole sodium, 7–8

## Ranitidine hydrochloride, 9

## Ribavirin, 94–95

## Rifampin, 106

## Rifaximin, 102–103, 109

**S**Spontaneous bacterial peritonitis  
(SBP)

- cefotaxime, 51–52
- ceftriaxone, 52–53
- cholangitis, 50
- ciprofloxacin, 54–55
- diverticulitis, 50
- levofloxacin, 53
- norfloxacin, 53–54

- sulfamethoxazole and  
trimethoprim, 55

## Sulfasalazine, 41, 42, 45

**T**

## Telbivudine, 87

## Tenofovir, 88

## Tetracycline, 62–63, 65–66

## Thiabendazole, 79

## Tinidazole, 74, 80

**U**

## Ulcerative colitis

- mild management, 38

- severe management, 39

## Ursodeoxycholic acid, 106

## Ursodiol, 99–100

**V**

## Valgancyclovir, 71

## Vancomycin, 59–60, 81

## Vasopressin, 15–16

Viral hepatitis. *See* HepatitisVitamin B 12 (cyanocobalamin),  
111–112

## Voriconazole, 66, 68

**W**

## Whipple's disease, 63

## Wilson's disease

- penicillamine, 97–98

- trientine, 98

- zinc sulfate, 98