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Donnatal Tablets (atropine sulfate/hyoscyamine sulfate/phenobarbital/scopolamine hydrobromide) - Drug Summary

Concordia Pharmaceuticals Inc.

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Donnatal
(atropine sulfate/hyoscyamine sulfate/phenobarbital/scopolamine hydrobromide)

THERAPEUTIC CLASS

Anticholinergic/barbiturate

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Irritable Bowel Syndrome

Adjunctive Therapy:
Elixir:
1 or 2 tsp tid or qid

Tab:
1 or 2 tabs tid or qid

Extentabs:
1 tab q12h. May give 1 tab q8h if indicated

Acute Enterocolitis

Adjunctive Therapy:
Elixir:
1 or 2 tsp tid or qid

Tab:
1 or 2 tabs tid or qid

Extentabs:
1 tab q12h. May give 1 tab q8h if indicated

Duodenal Ulcers

Adjunctive Therapy:
Elixir:
1 or 2 tsp tid or qid

Tab:
1 or 2 tabs tid or qid

Extentabs:
1 tab q12h. May give 1 tab q8h if indicated

PEDIATRIC DOSAGE & INDICATIONS

Irritable Bowel Syndrome

Adjunctive Therapy:
Elixir:
Initial:
4.5kg: 0.5mL q4h or 0.75mL q6h
9.1kg: 1mL q4h or 1.5mL q6h
13.6kg: 1.5mL q4h or 2mL q6h
22.7kg: 2.5mL q4h or 3.75mL q6h
34kg: 3.75mL q4h or 5mL q6h
45.4kg: 5mL q4h or 7.5mL q6h

Acute Enterocolitis

Adjunctive Therapy:
Elixir:
Initial:
4.5kg: 0.5mL q4h or 0.75mL q6h
9.1kg: 1mL q4h or 1.5mL q6h
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Duodenal Ulcers

Adjunctive Therapy:
Elixir:
Initial:
4.5kg: 0.5mL q4h or 0.75mL q6h
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34kg: 3.75mL q4h or 5mL q6h
45.4kg: 5mL q4h or 7.5mL q6h

DOSING CONSIDERATIONS

Hepatic Impairment
Use small initial doses

ADMINISTRATION

Oral route

Elixir
Use pediatric dosing device or oral syringe to measure the dose

HOW SUPPLIED

(Atropine/Hyoscyamine/Phenobarbital/Scopolamine) Elixir: (0.0194mg/0.1037mg/16.2mg/0.0065mg)/5mL [10mL, 4 fl. oz., 1 pint]; Tab: 0.0194mg/0.1037mg/16.2mg/0.0065mg; Tab, Extended-Release: (Extentabs) 0.0582mg/0.3111mg/48.6mg/0.0195mg

CONTRAINDICATIONS

Glaucoma; obstructive uropathy (eg, bladder-neck obstruction due to prostatic hypertrophy); obstructive GI disease (achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony in elderly/debilitated; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis (especially if complicated by toxic megacolon); myasthenia gravis; hiatal hernia associated w/ reflux esophagitis; acute intermittent porphyria; and patients in whom phenobarbital produces restlessness and/or excitement.

WARNINGS/PRECAUTIONS

Heat prostration can occur in high environmental temperatures. Diarrhea may be an early symptom of incomplete intestinal obstruction, especially w/ ileostomy or colostomy; treatment would be inappropriate and possibly harmful. May impair physical/mental abilities. Phenobarbital may be habit forming; avoid in patients prone to addiction or w/ history of physical and/or psychological drug dependence. Caution w/ autonomic neuropathy, renal disease, hyperthyroidism, coronary heart disease, CHF, arrhythmias, tachycardia, and HTN. May delay gastric emptying. Curare-like action may occur w/ overdosage. Abrupt withdrawal may produce delirium or convulsions in patients habituated to barbiturates. Elderly patients may react w/ symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug. (Elixir/Tab) May cause fetal harm when administered to pregnant women. Do not rely on the use of the drug in the presence of biliary tract disease complications. (Elixir [Mint]) Contains tartrazine, which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons; frequently seen in patients who also have aspirin sensitivity.

ADVERSE REACTIONS

Xerostomia, urinary hesitancy/retention, blurred vision, tachycardia, mydriasis, cycloplegia, increased ocular tension, loss of taste, headache, nervousness, drowsiness, weakness, dizziness, insomnia.

DRUG INTERACTIONS

Phenobarbital may decrease the effect of anticoagulants; may need larger doses of anticoagulant for optimal effect.

PREGNANCY AND LACTATION

Category D (Elixir/Tab), C (Extentabs); caution in nursing.

MECHANISM OF ACTION

Anticholinergic/barbiturate; provides peripheral anticholinergic/antispasmodic action and mild sedation.

ASSESSMENT

Assess for previous hypersensitivity to the drug or any of its components, diarrhea, ileostomy, colostomy, history of physical and/or psychological drug dependence, biliary tract disease, hepatic dysfunction, pregnancy/nursing status, possible drug interactions, and any other conditions where treatment is contraindicated or cautioned.

MONITORING

Monitor for signs/symptoms of heat prostration, drowsiness, blurred vision, constipation, diarrhea, urinary hesitancy/retention, hypersensitivity reactions, and other adverse reactions.

PATIENT COUNSELING

Counsel about possible side effects and advise to notify physician if any occur. Inform that the drug may be habit forming. If drowsiness or blurring of vision occurs, warn patients not to engage in activities requiring mental alertness (eg, operating a motor vehicle or other machinery) and not to perform hazardous work. Inform that treatment may decrease sweating, resulting in heat prostration, fever, or heat strokes. (Elixir/Tab) Advise to notify physician if pregnant or intending to become pregnant during therapy; apprise of the potential hazard to the fetus.

STORAGE

20-25°C (68-77°F). Protect from light and moisture. (Elixir) Avoid freezing.

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