HYOSCYAMINE SULFATE- hyoscyamine sulfate tablet, extended release
Chartwell RX, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

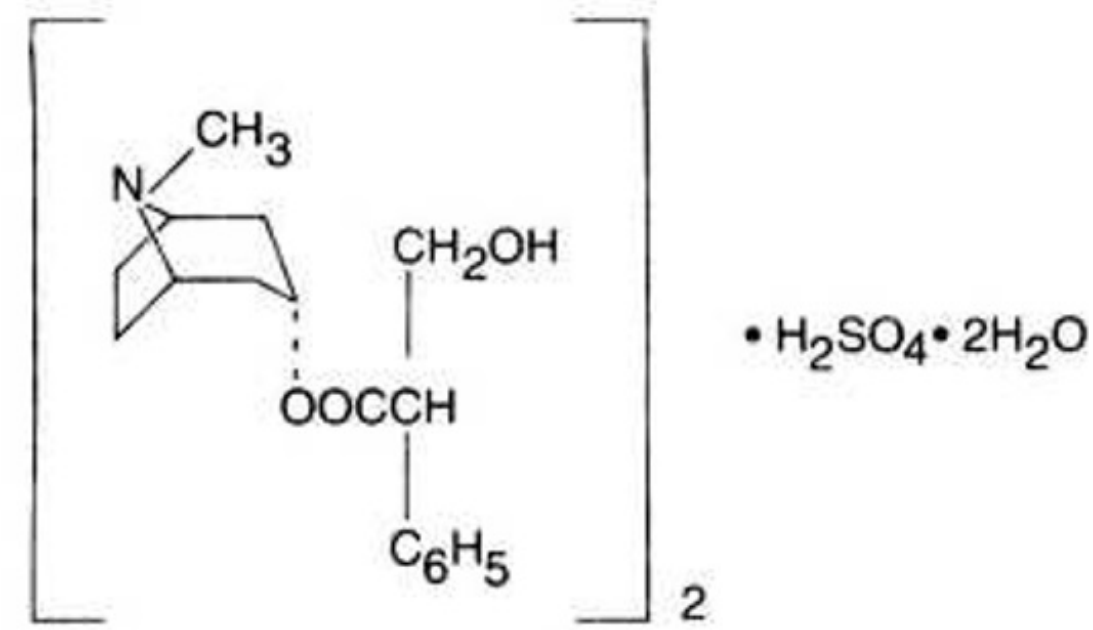
Hyoscyamine Sulfate Extended-Release Tablets

Rx Only

DESCRIPTION

Hyoscyamine Sulfate Extended-Release Tabletscontain 0.375 mg of hyoscyamine sulfate in a formulation designed for oral b.i.d. dosage.

Hyoscyamine sulfate is one of the principal anticholinergic/antispasmodic components of belladonna alkaloids. The empirical formula is $(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot 2H_2O$ and the molecular weight is 712.85. Chemically, it is benzeneacetic acid, (α-(hydroxymethyl)-,8-methyl-8-azabicyclo [3.2.1.] oct-3-yl ester, [3(S)-endo]-,sulfate (2:1), dihydrate with the following structure:



Hyoscyamine Sulfate Extended-Release Tabletsalso contain as inactive ingredients: microcrystalline cellulose, Hydroxypropyl cellulose, colloidal silicon dioxide, and magnesium stearate.

CLINICAL PHARMACOLOGY

Hyoscyamine Sulfate inhibits specifically the actions of acetylcholine on structures innervated by postganglionic cholinergic nerves and on smooth muscles that respond to acetylcholine but lack cholinergic innervation. These peripheral cholinergic receptors are

present in the autonomic effector cells of the smooth muscle, cardiac muscle, the sinoatrial node, the atrioventricular node, and the exocrine glands. At therapeutic doses, it is completely devoid of any action on autonomic ganglia. Hyoscyamine sulfate inhibits gastrointestinal propulsive motility and decreases gastric acid secretion. Hyoscyamine sulfate also controls excessive pharyngeal, tracheal and bronchial secretions.

Hyoscyamine sulfate is absorbed totally and completely by oral administration. Once absorbed, hyoscyamine sulfate disappears rapidly from the blood and is distributed throughout the entire body. The half-life of hyoscyamine sulfate is 2 to 3½ hours. Hyoscyamine sulfate is partly hydrolyzed to tropic acid and tropine but the majority of the drug is excreted in the urine unchanged within the first 12 hours. Only traces of this drug are found in breast milk. Hyoscyamine sulfate passes the blood brain barrier and the placental barrier.

Hyoscyamine sulfate extended-release tablets release 0.375 mg hyoscyamine sulfate at a controlled and predictable rate for 12 hours. The mean peak plasma concentration occurred at 4.20 hours. The mean (±SEM) apparent plasma elimination half-life is 7.47 hours (±0.60). Tablets may not completely disintegrate and may be excreted by some patients.

INDICATIONS AND USAGE

Hyoscyamine sulfate is effective as adjunctive therapy in the treatment of peptic ulcer. It can also be used to control gastric secretion, visceral spasm and hypermotility in spastic colitis, spastic bladder, cystitis, pylorospasm, and associated abdominal cramps. May be used in functional intestinal disorders to reduce symptoms such as those seen in mild dysenteries, diverticulitis, and acute enterocolitis. For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and functional gastrointestinal disorders. Also used as adjunctive therapy in the treatment of neurogenic bladder and neurogenic bowel disturbances (including the splenic flexure syndrome and neurogenic colon). Hyoscyamine sulfate is indicated along with morphine or other narcotics in symptomatic relief of biliary and renal colic; as a “drying agent” in the relief of symptoms of acute rhinitis; in the therapy of parkinsonism to reduce rigidity and tremors and to control associated sialorrhea and hyperhidrosis. May be used in the therapy of poisoning by anticholinesterase agents.

CONTRAINDICATIONS

Glaucoma; obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis); paralytic ileus, intestinal atony of elderly or debilitated patients; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon complicating ulcerative colitis; myasthenia gravis.

WARNINGS

In the presence of high environmental temperature, heat prostration can occur with drug use (fever and heat stroke due to decreased sweating). Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with this drug would be inappropriate and

possibly harmful. Like other anticholinergic agents, hyoscyamine sulfate may produce drowsiness, dizziness or blurred vision. In this event, the patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery or to perform hazardous work while taking this drug.

Psychosis has been reported in sensitive individuals given anticholinergic drugs. CNS signs and symptoms include confusion, disorientation, short term memory loss, hallucinations, dysarthria, ataxia, coma, euphoria, anxiety, fatigue, insomnia, agitation and mannerisms, and inappropriate affect. These CNS signs and symptoms usually resolve within 12 to 48 hours after discontinuation of the drug.

PRECAUTIONS

General:

Use with caution in patients with: autonomic neuropathy, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrythmias, hypertension, and renal disease. Investigate any tachycardia before giving any anticholinergic drug since they may increase the heart rate. Use with caution in patients with hiatal hernia associated with reflux esophagitis.

Information for Patients:

Like other anticholinergic agents, hyoscyamine sulfate may produce drowsiness, dizziness or blurred vision. In this event, the patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery or to perform hazardous work while taking this drug.

Use of hyoscyamine sulfate may decrease sweating resulting in heat prostration, fever or heat stroke; febrile patients or those who may be exposed to elevated environmental temperatures should use caution. Tablets may not completely disintegrate and may be excreted by some patients.

Drug Interactions:

Additive adverse effects resulting from cholinergic blockade may occur when hyoscyamine sulfate is administered concomitantly with other antimuscarinics, amantadine, haloperidol, phenothiazines, monoamine oxidase (MAO) inhibitors, tricyclic antidepressants or some antihistamines.

Antacids may interfere with the absorption of hyoscyamine sulfate. Administer hyoscyamine sulfate before meals; antacids after meals.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

No long-term studies in animals have been performed to determine the carcinogenic, mutagenic or impairment of fertility potential of hyoscyamine sulfate; however, 40 years of marketing experience with hyoscyamine sulfate shows no demonstrable evidence of a problem.

Pregnancy - Pregnancy Category C:

Animal reproduction studies have not been conducted with hyoscyamine sulfate. It is also not known whether hyoscyamine sulfate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hyoscyamine sulfate should

be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Hyoscyamine sulfate is excreted in human milk. Caution should be exercised when hyoscyamine sulfate is administered to a nursing woman.

Geriatric Use:

Reported clinical experience has not identified differences in safety between patients aged 65 and over and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

To report SUSPECTED ADVERSE REACTIONS, contact Chartwell RX, LLC. at 1-845-232-1683 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

ADVERSE REACTIONS

All of the following adverse reactions have been reported with hyoscyamine sulfate. Adverse reactions may include dryness of the mouth; urinary hesitancy and retention; blurred vision; tachycardia; palpitations; mydriasis; increased ocular tension; loss of taste; headache; nervousness; drowsiness; weakness; fatigue; dizziness; insomnia; nausea; vomiting; impotence; constipation; bloated feeling; abdominal pain; diarrhea; allergic reactions or drug idiosyncrasies; urticaria and other dermal manifestations; ataxia; speech disturbance; some degree of mental confusion and/or excitement (especially in elderly persons); short-term memory loss; hallucinations; and decreased sweating.

OVERDOSAGE

The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot dry skin, dizziness, dryness of the mouth, difficulty in swallowing, and CNS stimulation.

Measures to be taken are immediate lavage of the stomach and injection of physostigmine 0.5 to 2 mg intravenously and repeated as necessary up to a total of 5 mg. Fever may be treated symptomatically (tepid water sponge baths, hypothermic blanket). Excitement to a degree which demands attention may be managed with sodium thiopental 2% solution given slowly intravenously or chloral hydrate (100-200 mL of a 2% solution) by rectal infusion. In the event of progression of the curare-like effect to paralysis of the respiratory muscles, artificial respiration should be instituted and maintained until effective respiratory action returns.

In rats, the LD_{50} for hyoscyamine is 375 mg/kg. Hyoscyamine sulfate is dialyzable.

DOSAGE AND ADMINISTRATION

Dosage may be adjusted according to the conditions and severity of symptoms.

Adults And Pediatric Patients 12 Years Of Age And Older

1 to 2 tablets every 12 hours. Do not crush or chew tablets. Do not exceed 4 tablets in 24 hours.

HOW SUPPLIED

Hyoscyamine Sulfate Extended-Release Tablets, 0.375 mg are white, oval shaped, biconvex tablets debossed with " **CE**" on one side and " **223**" on the other side.

Bottles of 60 (NDC 62135-860-60)

Store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

Rx only.

Manufactured for:
Chartwell RX, LLC.
Congers, NY 10920

Rev. 06/2024

L72218

PRINCIPAL DISPLAY PANEL

Hyoscyamine Sulfate Extended-Release Tablets 0.375 mg - NDC 62135-860-60 - 60s Bottle Label

HYOSCYAMINE SULFATE
hyoscyamine sulfate tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62135-860
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYOSCYAMINE SULFATE (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.375 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	CE;223
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-860-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/05/2024	

Labeler - Chartwell RX, LLC (079394054)

Establishment

Name	Address	ID/FEI	Business Operations
Chartwell Pharmaceuticals Congers, LLC		118673447	manufacture(62135-860)