

## **HYOSCYAMINE SULFATE- hyoscyamine sulfate injection, solution**

### **BPI Labs LLC**

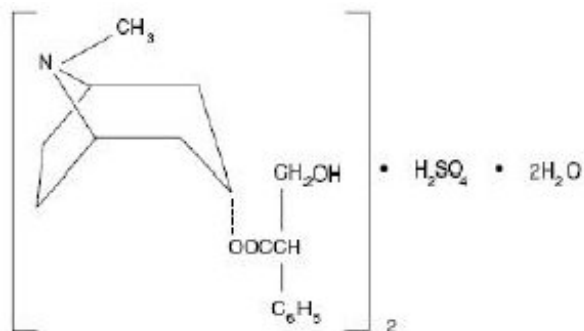
*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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### **DESCRIPTION**

Hyoscyamine sulfate injection, USP is a sterile solution containing 0.5 mg hyoscyamine sulfate per mL in water for injection.

Hyoscyamine sulfate Injection, USP 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,  $\alpha$ -(hydroxymethyl)-,8-methyl-8-azabicyclo [3.2.1.] oct-3-yl ester, [3(S)-endo]-, sulfate (2:1), dihydrate with the following structure:



The 1 mL vials contain as inactive ingredients: water for injection, pH is adjusted with hydrochloric acid when necessary.

### **CLINICAL PHARMACOLOGY**

Hyoscyamine sulfate Injection, USP 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. It is completely devoid of any action in the autonomic ganglia. Hyoscyamine sulfate Injection, USP inhibits gastrointestinal propulsive motility and decreases gastric acid secretion. Hyoscyamine sulfate Injection, USP also controls excessive pharyngeal, tracheal and bronchial secretions.

Hyoscyamine sulfate Injection, USP disappears rapidly from the blood and is distributed throughout the entire body. The half-life of Hyoscyamine sulfate Injection, USP is 31/2 hours. Hyoscyamine sulfate Injection, USP 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 Injection, USP passes the blood brain barrier and the placental barrier.

## **INDICATIONS AND USAGE**

Hyoscyamine sulfate Injection, USP is effective as adjunctive therapy in the treatment of peptic ulcer. In acute episodes, Hyoscyamine sulfate Injection, USP can be used to control gastric secretion, visceral spasm and hypermotility in spastic colitis, spastic bladder, cystitis, pylorospasm, and associated abdominal cramps. For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and functional gastrointestinal disorders. Also as adjunctive therapy in the treatment of neurogenic bladder and neurogenic bowel disturbances (including the splenic flexure syndrome and neurogenic colon). Parenterally administered Hyoscyamine sulfate Injection, USP is also effective in reducing gastrointestinal motility to facilitate diagnostic procedures such as endoscopy or hypotonic duodenography. Hyoscyamine sulfate Injection, USP may be used to reduce pain and hypersecretion in pancreatitis, in certain cases of partial heart block associated with vagal activity, and as an antidote for poisoning by anticholinesterase agents.

### *In Anesthesia:*

Hyoscyamine sulfate Injection, USP is indicated as a pre-operative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions, to reduce the volume and acidity of gastric secretions, and to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation. Hyoscyamine sulfate Injection, USP protects against the peripheral muscarinic effects such as bradycardia and excessive secretions produced by halogenated hydrocarbons and cholinergic agents such as physostigmine, neostigmine, and pyridostigmine given to reverse the actions of curariform agents.

### *In Urology:*

Hyoscyamine sulfate Injection, USP may also be used intravenously to improve radiologic visibility of the kidneys. It is also indicated along with morphine or other narcotics in symptomatic relief of biliary and renal colic.

## **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 and myocardial ischemia.

## **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 Injection, USP may produce drowsiness 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, decreased 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 arrhythmias, 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.

Prolonged use of anticholinergics may decrease or inhibit salivary flow, thus contributing to the development of caries, periodontal disease, oral candidiasis, and discomfort.

### *Information for Patients:*

Like other anticholinergic agents, Hyoscyamine sulfate Injection, USP may cause drowsiness, dizziness or blurred vision; patients should observe caution before driving, using machinery or performing other tasks requiring mental alertness.

Use of Hyoscyamine sulfate Injection, USP 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.

### *Drug Interactions:*

Additive adverse effects resulting from cholinergic blockade may occur when Hyoscyamine sulfate Injection, USP is administered concomitantly with other anticholinergics, antimuscarinics, amantadine, cyclopropane, haloperidol, ketoconazole, metoclopramide, monoamine oxidase (MAO) inhibitors, opioid (narcotic) analgesics, phenothiazines, potassium chloride, tricyclic antidepressants and some antihistamines.

### *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 Injection, USP.

### *Pregnancy - Pregnancy Category C:*

Animal reproduction studies have not been conducted with Hyoscyamine sulfate Injection, USP. It is also not known whether Hyoscyamine sulfate Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hyoscyamine sulfate injection should be given to a pregnant woman only if clearly needed.

### *Nursing Mothers:*

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

### *Pediatric Use:*

Infants and young children are especially susceptible to the toxic effects of anticholinergics. Close supervision is recommended for infants and children with spastic paralysis or brain damage since an increased response to anticholinergics has been reported in these patients and dosage adjustments are often required.

When anticholinergics are given to children where the environmental temperature is high, there is a risk of a rapid increase in body temperature because of these medications' suppression of sweat gland activity.

A paradoxical reaction characterized by hyperexcitability may occur in children taking large doses of anticholinergics.

#### *Geriatric Use:*

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.

Geriatric patients may respond to usual doses of anticholinergics with excitement, agitation, drowsiness or confusion.

Geriatric patients are especially susceptible to the anticholinergic side effects, such as constipation, dryness of mouth, and urinary retention (especially in males). Caution is also recommended when anticholinergics are given to geriatric patients, because of the danger of precipitating undiagnosed glaucoma.

Memory may become severely impaired in geriatric patients, especially those who already have memory problems, with the continued use of anticholinergics since these drugs block the actions of acetylcholine, which is responsible for many functions in the brain, including memory functions.

## **ADVERSE REACTIONS**

Not all of the following adverse reactions have been reported with hyoscyamine sulfate. The following adverse reactions have been reported for pharmacologically similar drugs with anticholinergic/antispasmodic action.

Adverse reactions may include dryness of the mouth; urinary hesitancy and retention; blurred vision; tachycardia; palpitations; mydriasis; cycloplegia; increased ocular tension; loss of taste; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; 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); and decreased sweating.

**To report SUSPECTED ADVERSE REACTIONS, contact BPI Labs, LLC, at (727-471-0850) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **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 to 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<sub>50</sub> for hyoscyamine is 375 mg/kg. Hyoscyamine sulfate Injection, USP is dialyzable.

## **DOSAGE AND ADMINISTRATION**

The dose may be administered subcutaneously, intramuscularly, or intravenously without dilution. As with all parenteral drug products, Hyoscyamine sulfate injection, USP should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

### **Gastrointestinal Disorders:**

The usual adult recommended dose is 0.5 to 1 mL (0.25 to 0.5 mg). Some patients may need only a single dose; others may require administration two, three, or four times a day at four hour intervals.

### **Diagnostic Procedures:**

The usual adult recommended dose is 0.5 to 1 mL (0.25 to 0.5 mg) administered intravenously 5 to 10 minutes prior to the diagnostic procedure.

### **Anesthesia:**

#### **Adults and pediatric patients over 2 years of age:**

As a pre-anesthetic medication, the recommended dose is 5 µg (0.005 mg) per kg of body weight. This dose is usually given thirty to sixty minutes prior to the anticipated time of induction of anesthesia or at the time the pre-anesthetic narcotic or sedatives are administered.

Hyoscyamine sulfate injection, USP may be used during surgery to reduce drug-induced bradycardia. It should be administered intravenously in increments of 0.25 mL and repeated as needed.

To achieve reversal of neuromuscular blockade, the recommended dose is 0.2 mg (0.4 mL) Hyoscyamine sulfate injection USP for every 1 mg neostigmine or the equivalent dose of physostigmine or pyridostigmine.

## **HOW SUPPLIED**

Hyoscyamine sulfate injection USP (Hyoscyamine sulfate injection USP, 0.5 mg/mL), is available in 1 mL vials.

1 mL vials – Box of 5 NDC 54288-111-05

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

Also available as:

| Product  | Dosage Strength | Package Size | NDC                 |
|--|-----------------|--------------|---------------------|
| Hyoscyamine sulfate injection, USP<br>54288-111-05 | 0.5 mg/mL       |              | 5 Vials (1 mL Each) |

## PRINCIPAL DISPLAY PANEL - 0.5 mg/mL

### NDC 54288-111-01

Hyoscyamine sulfate Injection, USP

**0.5 mg** hyoscyamine sulfate, USP per mL in water for injection.

5 Vials  
(1 mL each)

Rx only

### DOSAGE AND ADMINISTRATION:

See package insert for further information.


Store at 25°C (77°F), excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

### Distributed by:

BPI Labs LLC  
12393 Belcher Rd S

Largo FL 33773


R-1907 LI01I



NDC 54288-111-01  
**Hyoscyamine Sulfate  
Injection, USP**  
**0.5 mg/mL**  
0.5 mg hyoscyamine sulfate, USP  
per mL in water for injection.  
Single-Use Vial      Rx Only

**DOSAGE AND ADMINISTRATION**  
See package insert for further information.  
Store at 25°C (77°F); excursions permitted  
to 15° - 30°C (59° - 86°F) [See USP  
Controlled Room Temperature].

**Manufactured By: BPI LABS**  
12393 Belcher Rd S Largo FL 33773  
L1111L-01    R-1902  
Batch: XXXXXXXX Exp: XX/XXXX



3 54288 11101 0

**Carton: NDC 54288-111-05**

Hyoscyamine sulfate Injection, USP

0.5 mg hyoscyamine sulfate, USP per mL in water for injection.

Rx only



## HYOSCYAMINE SULFATE

hyoscyamine sulfate injection, solution

### Product Information

|                         |                         |                    |               |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type            | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:54288-111 |
| Route of Administration | SUBCUTANEOUS            |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength   | Strength       |
|---|---------------------|----------------|
| <b>HYOSCYAMINE SULFATE</b> (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X) | HYOSCYAMINE SULFATE | 0.5 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name                 | Strength |
|---------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0KO0R) |          |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:54288-111-05 | 5 in 1 CARTON   | 10/18/2019           |                    |
| 1 | NDC:54288-111-01 | 1 mL in 1 VIAL; Type 1: Convenience Kit of Co-Package |                      |                    |

## Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug<br>other |  | 10/18/2019           |                    |

**Labeler** - BPI Labs LLC (078627620)

## Establishment

| Name         | Address | ID/FEI    | Business Operations   |
|--------------|---------|-----------|---|
| BPI Labs LLC |         | 078627620 | manufacture(54288-111) , label(54288-111) , analysis(54288-111) |

Revised: 10/2023

BPI Labs LLC