

SCOPOLAMINE HYDROBROMIDE**סקופולמין הידרוברומיד****INJECTION**

להזרקה תת עורית או לתוך השריר
להזרקה לתוך הוריד לאחר מיהול מתאים

Composition

Each ampoule of 1 ml contains:

Active Ingredient

Scopolamine hydrobromide 0.25 mg

Other Ingredient

Water for injection.

Action

Scopolamine is a parasympatholytic agent possessing central and peripheral actions. In the central nervous system (CNS), it produces depression of the cerebral cortex, especially of motor areas, and acts as a powerful hypnotic.

When administered prior to general anesthesia, scopolamine calms the patient, reduces secretions, produces amnesia, diminishes some of the side effects of the anesthetic and assists in the induction process.

In conjunction with morphine, scopolamine produces a condition of amnesia and partial analgesia known as 'twilight sleep'.

Indications

Scopolamine is used in cases where antimuscarinic action is desired, such as in premedication, where reduction of excitement and production of amnesia, in conjunction with morphine or pethidine, are desired.

Contraindications

Known hypersensitivity to the drug.

Scopolamine should not be administered to patients with symptoms of prostatism, or with narrow-angle glaucoma, tachycardia, paralytic ileus, obstructive uropathy or myasthenia gravis.

Antimuscarinics are contraindicated in the presence of tachycardia secondary to cardiac insufficiency or thyrotoxicosis. Antimuscarinics are also contraindicated in patients with acute hemorrhage whose cardiovascular status is unstable.

Warnings*Use in Pregnancy*

Scopolamine crosses the placenta; safety of use in pregnancy has not been established.

Administration before the onset of labor may cause CNS depression and hemorrhage in neonates.

Use in Breastfeeding

Safety of use in breastfeeding has not been established. However, as an anticholinergic, scopolamine may inhibit lactation.

Use in Pediatrics

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 risk of a rapid increase in body temperature because of these medications' suppression of sweat gland activity.

Use in the Elderly

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 of this medicine.

Adverse Reactions

Average or large doses may cause dryness of the mouth, nose, throat or skin, drowsiness, accelerated pulse rate, flushing, bradycardia, mydriasis, blurred vision, urinary retention, constipation, and raised intraocular pressure, decreased sweating, temporary loss of memory, redness or other signs of irritation at injection site.

Precautions

Use with caution in patients with prostatic hypertrophy, pyloric or intestinal obstruction, coronary insufficiency, or cardiac failure.

Administration of scopolamine is not recommended in asthmatic patients. Tachycardia may result from vagal inhibition which may induce angina pectoris in patients with coronary heart disease. The drug should be used with caution in patients above 40 years of age because of the increased incidence of glaucoma in this age group.

Patients sensitive to one belladonna alkaloid or derivative may be sensitive to the other belladonna alkaloids or derivatives also.

Drug Interactions

Concurrent use of scopolamine with other CNS depression-producing medications may potentiate the effect of either these medications or scopolamine, resulting in additive sedation.

Concurrent intravenous administration of anticholinergics with cyclopropane anesthesia may result in ventricular arrhythmias.

Concurrent use of scopolamine with anticholinergics or other medications possessing anticholinergic activity may lead to intensification of the anticholinergic effects.

Dosage and Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

This drug should be administered S.C or.I.M. It may be administered I.V., after suitable dilution with sterile water for injection.

For direct I.V. administration, scopolamine hydrobromide injection should be diluted with Water for Injection prior to administration.

When given as a preoperative medication, scopolamine hydrobromide injection should be administered 30-60 minutes prior to the anticipated time of induction of anesthesia or at the time other preanesthetic medications (e.g. opiates, sedatives) are administered.

Recommended dosage:

Adults

0.32 mg-0.65 mg.

Children

Up to 4 months of age: Use is not recommended.

4 months of age and above: 0.006 mg/kg/body weight.

Alternatively:

4 to 7 months of age: 100 mcg (0.1 mg)

7 months to 3 years of age: 150 mcg (0.15 mg)

3 to 8 years of age: 200 mcg (0.2 mg)

8 to 12 years of age: 300 mcg (0.3 mg)

Drug Registration No.:

Scopolamine Hydrobromide 0.25 mg: 046 75 23657 00

Scopolamine Hydrobromide 0.5 mg: 66.882.3342

TEVA

Manufacturer

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