



PrATROPINE

ATROPINE SULFATE Ophthalmic Solution, Mfr. Std. 1%

DESCRIPTION AND ACTIONS

Atropine sulfate is a long acting mydriatic and cycloplegic drug. Atropine blocks the action of acetylcholine resulting in relaxation of the cholinergically innervated sphincter muscle of the iris and the accommodative ciliary muscle of the lens. Atropine produces dilation of the pupil (mydriasis) and paralysis of accommodation (cycloplegia).

The maximum mydriatic effect of atropine sulfate occurs in 30-40 minutes and maximum cycloplegia occurs in several hours. Mydriasis generally lasts 7-12 days and cycloplegia persists for up to 14 days or longer. The onset of effect may be slower and the duration longer in individuals with heavily pigmented eyes.

NON-MEDICINAL INGREDIENTS

Benzalkonium chloride 0.01% as preservative, disodium edetate, hydroxypropyl methylcellulose, boric acid, and purified water. Hydrochloric acid may be used to adjust pH.

INDICATIONS

Atropine Sulfate Ophthalmic Solution is used to produce mydriasis and cycloplegia for examination of the retina and optic disk and accurate measurement of refractive errors. It is also used in the management of pain and inflammation of the iris and uveal tract, and pain associated with trauma of the cornea and sclera due to surgery, laceration or ulceration.

CONTRAINDICATIONS

Atropine Sulfate Ophthalmic Solution is contraindicated in patients with known or suspected angle closure glaucoma. It is also contraindicated in patients with known hypersensitivity to the drug, belladonna alkaloids or any ingredient in the formulation.

WARNINGS

Intraocular pressure should be checked periodically with prolonged use.

PRECAUTIONS

Atropine sulfate should be used with extreme caution, if at all, in infants and small children. The patient should be advised to take care to avoid contamination of the tip of the applicator bottle during use and to replace cap after use.

May cause blurred vision and increased sensitivity of the eyes to light. Patient should not drive or engage in any hazardous activities while the pupils are dilated.

ADVERSE EFFECTS

Atropine sulfate may cause increased intraocular pressure. Prolonged administration to the eyes may cause local irritation, hyperemia, edema, follicular conjunctivitis or dermatitis. Adverse effects may be more likely in geriatric patients, since they may be sensitive to the systemic effects of atropine.

DOSAGE AND ADMINISTRATION

To avoid excessive systemic administration, the patient should be shown how to apply finger pressure to the lacrimal sac for 1-2 minutes after instillation.

Mydriasis and Cycloplegia Adults: 1 drop into the eye(s) 1 hour before the procedure.

Pupillary Dilation in

Acute Inflammatory Conditions of the Iris and Uveal Tract: 1 drop instilled in the eye(s) up to 3 times daily.

Prevention of Synechiae: 1 drop instilled in the eye(s) up to 3 times daily.

Prior to intraocular Surgery: Instill 1 drop 3 times daily for 24 hours prior to surgery.

STORAGE

Store at controlled room temperature (15-30°C).

SUPPLIED

Atropine Sulfate Ophthalmic Solution is available in a 15mL plastic squeeze bottle with an applicator tip.

DIN 02023695

Pharma Stulln Inc.

6500 TransCanada highway, Suite 400,

Pointe-Claire (Quebec) H9R 0A5

+1 514 426-6179

E-mail: info@pharmastulln.ca

Revised 05/18

Version: 06

Size: 132mm x 270mm

