


Maruti Print & Pack  
Date 29.07.2021

190 X 110 mm

 **EVEREST**  
Patient Leaflet : Information for the user

**Atropine Eye Drops BP (1% w/v)**  
**EVAPIN EYE DROPS 5ml**

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**COMPOSITION**  
Each ml contains:  
Atropine Sulphate BP 1% w/v  
Chlorobutanol BP 0.5% w/v  
(As preservative)  
Isotonic Buffered  
Aqueous Base q.s.

**Description**  
EVAPIN is a clear, sterile ophthalmic solution of Atropine Sulphate supply in container. It belongs to groups of medicines called Anticholinergic i.e. mydriatics (medicines that widen the pupil) and cycloplegics (medicines used to relax the muscles which enable the eyes to focus).

**Pharmacodynamics**  
Atropine sulphate is a competitive antagonist of acetylcholine at postganglionic cholinergic (parasympathetic) nerve endings. It does not discriminate between the recently discovered muscarinic receptor sub types M1 (in parasympathetic ganglia of the submucous plexus, with high affinity for selecting antimuscarinic pirenzepine) and M2 (low affinity for pirenzepine and occurring predominantly in heart and smooth muscle).

**Pharmacokinetics**  
Atropine is absorbed by mucous membranes but less readily from the eye and skin, although significant toxicity can sometimes occur through absorption of excessive eye drops. Atropine has a volume of distribution of 1 –6 L/kg. Protein binding is moderate, with approximately 50% of the drug bound in plasma. Its plasma clearance is 8ml/min/kg. Only traces of atropine are found in breast milk.

The drug readily crosses the blood–brain barrier and may cause confusion and delirium post-operatively. It crosses the placenta readily. Atropine is metabolized by hepatic oxidation and conjugation to inactive metabolites, with about 2% undergoing hydrolysis to tropine and tropic acid. About 30% of the dose is excreted unchanged in the urine. Only trace amounts of the dose are eliminated in the faeces.

**Therapeutic Indication**  
EVAPIN is indicated for mydriatic and cycloplegic and penalization of the healthy eye in the treatment of amblyopia.

**Dosage and Administration**  
Instill one drop in the affected eye 3 times a day for 7 days. Do not touch your eye or eyelid, surrounding areas or other surfaces with the bottle tip. It could contaminate the drops.

**Instruction for use**  
Apply EVAPIN in the following way:  
1. Wash your hands. Tilt your head back and look at the ceiling.  
2. Gently pull the lower eyelid down until there is a small pocket.  
3. Turn the bottle upside down and gently press the bottle to release drops into eyes that needs treatment.  
4. Let go of the lower lid, and close your eye for 30 seconds.  
5. To avoid contamination, do not let the tip of the dropper touch your eye or anything else.  
6. Replace and tighten the cap straight after use.

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**Overdose**  
Systemic reactions to topical atropine are unlikely at normal doses. Symptoms include anticholinergic effects, cardiovascular changes (tachycardia, atrial arrhythmias, atrio-ventricular dissociation) and CNS effects (confusion, ataxia, restlessness, hallucination, convulsions). Treatment is supportive.

**Contraindications**

- Hypersensitivity to Atropine Sulphate, or to any components of the preparation
- Due to the risk of precipitating an acute attack, do not use in cases of confirmed narrow-angle glaucoma or where latent narrow angle glaucoma is suspected. If in doubt it is recommended that an alternative preparation is used.

**Warning and Precautions**

- The protracted mydriasis which is difficult to reverse, may be a disadvantage.
- Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.)
- Do not use if solution changes colour or becomes cloudy.
- Do not use the eye drops with contact lenses.
- To avoid contamination do not touch tip of container to any surface. Replace cap after using.
- Do not use if packaging shows evidence of tampering.

**Pregnancy and Lactation**  
The safety for use in pregnancy and lactation has not been established, therefore, use only when directed by a physician.


**Effect on ability to drive and use medicines**  
EVAPIN may cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery until vision is clear.

**Drug Interaction**  
The use of atropine and monoamine oxidase inhibitors (MAOI) is generally not recommended because of the potential to precipitate hypertensive crisis.

**Adverse Effects**  
Side effects rarely occur but include anticholinergic effects such as dry mouth and skin, flushing, increased body temperature, urinary symptoms, gastrointestinal symptoms and tachycardia. These effects are more likely to occur in infants and children. If you use Evapin Eye Drops for a long period of time may experience: Local irritation (itching around the eye), temporary stinging, blood shot eyes (hyperaemia), swelling of eyelids (Oedema), redness of eye (conjunctivitis), Increase in pressure in eyes (glaucoma).

**Presentation**  
EVAPIN are supplied in 5ml plastic dropper bottle

**Storage and other information**  
Store in a cool, dark and dry place. Use the solution within one month after opening the container. Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate the solution.

 **EVEREST**  
Manufactured by :  
**Everest Parenterals Pvt. Ltd.**  
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