Important information. Please read carefully.

MYOPINE

Eye Drops 0.025%w/v

COMPOSITION

Each 5ml contains Atropine Sulphate 0.025% w/v.
Benzalkonium Chloride 0.01% w/v as preservative.

PHARMACODYNAMICS

Antimuscarinic drugs such as atropine are competitive inhibitors of the actions of acetylcholine at the muscarinic receptors of autonomic effector sites innervated by parasympathetic (cholinergic postganglionic) nerves; they are also inhibitors of the action of acetylcholine on smooth muscle lacking cholinergic innervation.

PHARMACOKINETICS

Atropine is readily absorbed from the gastrointestinal tract. It is also absorbed from mucous membranes, the eye, and to some extent through intact skin. It is rapidly cleared from the blood and is distributed throughout the body. It crosses the blood-brain barrier. It is incompletely metabolised in the liver and is excreted in the urine as unchanged drug and metabolites. A half-life of about 4 hours has been reported. Atropine crosses the placenta and traces appear in breast milk.

INDICATIONS

Control progression of Myopia

DOSAGE AND ADMINISTRATION

One drop topically in eye(s) once at night.

CONTRAINDICATIONS

Persons with glaucoma or a tendency toward glaucoma, and with hypersensitivity to belladonna alkaloids.

WARNINGS AND PRECAUTIONS

For external use only. Excessive use may produce symptoms of systemic atropine poisoning.

INTERACTIONS WITH OTHER MEDICAMENTS

The effects of atropine and other antimuscarinics may be enhanced by use with other drugs having antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics, and tricyclic antidepressants. Inhibition of drug-metabolising enzymes by MAOIs may possibly enhance the effects of antimuscarinics. The reduction in gastric motility caused by antimuscarinics may affect the absorption of other drugs. Antimuscarinics may also antagonise the gastrointestinal effects of cisapride, domperidone, and metoclopramide. Antimuscarinics and parasympathomimetics may counteract each other's effects.

PREGNANCY AND LACTATION

This product should be used with caution during pregnancy or lactation unless potential benefits outweigh the potential risks.

Pregnancy

Atropine crosses the placenta.

Lactation

Traces may appear in breast milk. No adverse effects have been observed in breast-feeding infants whose mothers were receiving atropine.

SIDE EFFECTS

May associated with stinging sensation on instillation.

May cause allergy (itch, irritation, and redness), blurring of near vision and glare in some children.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE

Excessive use or hyper-susceptibility to belladonna alkaloids may produce symptoms of atropine poisoning (palpitation, hot dry skin, dizziness, tremor, unsteady gait and change in level of consciousness). You should consult a physician if your child demonstrate these symptoms.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

May cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery until vision is clear.

Shelf-life

The expiry date is indicated on the packaging.

STORAGE CONDITION

Store below 30°C.

PRODUCT DESCRIPTION

Clear, colourless, sterile solution.

Available in 5ml plastic dropper bottle.

KEEP OUT OF REACH OF CHILDREN

For further information, please consult your pharmacist or physician.

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Manufacturer and Product Registration Holder

Xepa-Soul Pattinson (Malaysia) Sdn Bhd

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