MYOPINE Eye Drops 0.01% w/v

Each 5ml contains Atropine Sulphate 0.01% w/v

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What MYOPINE Eye Drops is used for

MYOPINE Eye Drops is used to slow down the worsening of short-sightedness or near-sightedness (known as Myopia) in children aged 6 to 12 years old with documented myopic progression of more than 0.5 diopters (D) per year.

How MYOPINE Eye Drops works

MYOPINE Eye Drops contains atropine sulphate which belongs to groups of medicines called mydriatics (medicines that widen the pupil) and cycloplegics (medicines used to relax the muscles which enable the eyes to focus).

Before you use MYOPINE Eye Drops

- *When you must not use it*

Do not take this medicine if:

- you are allergic or have hypersensitivity to atropine sulfate, belladonna alkaloids, or any other ingredients of this medicine (listed in Product Description).
- you suffer from increased pressure in the eye (glaucoma or a tendency to glaucoma).

- *Before you start to use it*

Talk to your doctor or pharmacist before using MYOPINE eye Drops if:

- you are taking any eye medicines or other medicines
- you are pregnant, trying to become pregnant or you are breast-feeding

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

There are no or limited amount of data from the use of MYOPINE Eye Drops in pregnant women. It is not recommended during pregnancy and in women of childbearing potential not using contraception. MYOPINE Eye Drops should not be used during breast-feeding. Studies have not been performed to evaluate the effects of topical ocular administration of atropine on fertility.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Although no drug interactions were reported in pooled clinical studies, other medicines may interfere with the actions of MYOPINE Eye Drops. Tell your doctor if you are using any of the following medicines with antimuscarinic properties: amantadine, some antihistamines, phenothiazine, antipsychotics and tricyclic antidepressants.

How to use MYOPINE Eye Drops

- *How much to use*

Always use MYOPINE Eye Drops as instructed. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose for children aged 6-12 years old is:

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

Instructions for use

MYOPINE Eye Drops are only to be used in the eyes.

- after cap is removed, if tamper evident snap collar is loose, remove before using product.
- gently pull the lower eyelid downwards and outwards
- place one drops into the gap between the lid and the eye
- blink a few times
- to prevent contamination of the dropper tip and solution, take care not to touch the dropper tip on the eyelid or any other surface
- Keep the bottle tightly closed when not in use

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Use MYOPINE Eye Drops for the duration that the doctor recommends.

- *If you forget to use it*

Do not use a double dose to make up for the forgotten dose. Use the next dose at the usual time.

- *If you use too much (overdose)*

If you feel you may have used too much of your medicine, you can flush it from the eye(s) with lukewarm water. Contact your doctor or your nearest hospital casualty unit.

While you are using it

- *Things you must do*

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using MYOPINE Eye Drops.

Tell your doctor immediately if you become pregnant while using this medication.

Take MYOPINE Eye Drops only with a doctor's prescription.

- *Things you must not do*

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

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Do not give MYOPINE Eye Drops to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

- MYOPINE Eye Drops are for external use only.
  Do not swallow. If you swallow MYOPINE Eye Drops tell your doctor or nearest hospital casualty unit **immediately**.
- You should wash your hands after using the eye drops and care should be taken to avoid getting the product into the mouth
- MYOPINE Eye Drops should be discarded 4 weeks after first opening.

Side effects

Like all medicines, MYOPINE Eye Drops can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

Possible side effects include:

- a stinging sensation when the eye drop is applied
- increased sensitivity to light (photophobia).
- blurring of near vision (reduction in visual acuity) and glare
- local allergic reaction (itch, irritation and redness)

If these side effects occur you should stop using MYOPINE Eye Drops and speak to your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of MYOPINE Eye Drops

- *Storage*

Keep out of the reach and sight of children.

Store below 30°C.

Do not use MYOPINE Eye Drops after the expiry date which is stated on the bottle label.
Once you have opened the bottle it should be discarded after four weeks.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

MYOPINE Eye Drops is a clear, colourless, sterile solution supplied in a plastic dropper bottle containing 5ml of the eye drops.

- *Ingredients*

- Active ingredient:

Each 5ml contains Atropine Sulphate 0.01% w/v.

- Inactive ingredients:

Benzalkonium Chloride 0.01% w/v as preservative, boric acid, hypromellose, disodium acetate and purified water.

- *MAL number:*

MAL24096021ACZ

Manufacturer

Xepa-Soul Pattinson (Malaysia) Sdn Bhd
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Product Registration Holder

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