

PACKAGE LEAFLET: INFORMATION FOR THE USER

ISOPTO TEARS

5 mg / 1 ml, eye drops, solution

HYPROMELLOSE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What ISOPTO TEARS is and what it is used for
2. Before you take ISOPTO TEARS
3. How to take use ISOPTO TEARS
4. Possible side effects
5. How to store ISOPTO TEARS
6. Further information

1. WHAT ISOPTO TEARS IS AND WHAT IT IS USED FOR

ISOPTO TEARS eye drops, solution containing 5 mg / 1 ml Hypromellose which acts as artificial tears.

ISOPTO TEARS is used to treat dry eyes.

ISOPTO TEARS is used for the treatment of dry eye syndrome and reduced tearing, inflammation of the cornea and dry inflammation of conjunctiva accompanied by inflammation of the cornea. It may also be used to moisten hard contact lenses.

Isopto Tears contains a substance that makes the medicine slightly denser than water and allows the medicine to lubricate the eye.

2. BEFORE YOU TAKE ISOPTO TEARS

Do not take ISOPTO TEARS

- If you are allergic to Hypromellose or to other ingredients of this medicine (see section 6)

Take special care with ISOPTO TEARS

Warnings and precautions:

- Contact your doctor or pharmacist before applying ISOPTO TEARS

- If you experience headache, eye pain, changes in vision, irritation of the eye, redness that does not stop or it gets worse or continues, stop taking the medicine and consult your doctor.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

Before you start taking some medicine, consult your doctor or pharmacist.

Driving and using machines

You may experience blurred vision after using ISOPTO PLAIN. Do not drive or operate hazardous machinery unless your vision is clear.

Important information

There is a preservative in ISOPTO PLAIN (benzalkonium chloride) that can discolor soft contact lenses. Do not use the drops while wearing contact lenses. Wait at least 15 minutes after use before putting your lenses back in.

3. HOW TO TAKE ISOPTO TEARS

Always use ISOPTO PLAIN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Remove the loose collar from the cap when the bottle is first opened.

The recommended dose for adults and children is:

The usual dose is 1 or 2 drops in each affected eye 3 or 4 times daily or as specified by your doctor or pharmacist.

If the irritation in your eyes does not get better or gets worse after 3 days or if you start to experience headache, eye pain, vision changes or continued redness in your eyes, stop using ISOPTO PLAIN and see your doctor.

ISOPTO TEARS drops are packed in specially designed packaging with dropper for easier application. Follow the instructions below for the correct application of this medicine.

To prevent contamination of the contents do not touch the surrounding areas with dropper.

By following next 10 steps you will ensure the correct application and the best effectiveness of the medicine.



- 1) Wash your hands before you start.
- 2) Twist off the bottle cap.
- 3) Hold the bottle pointing down, between your thumb and fingers.
- 4) Tilt your head back.
- 5) Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here.
- 6) Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- 7) Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- 8) Gently press on the base of the bottle to release one drop at a time.
- 9) Do not squeeze the bottle, only a gentle press on the bottom is needed.
- 10) If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.

If a drop misses your eye, try again.

If you forget to take ISOPTO PLAIN, do not worry, just take it as soon as possible.

If you use other drops or ointments, wait at least 5 minutes between applying each medicine. Ointments should be applied last.

If you use more ISOPTO PLAIN than you should, it can be washed out of your eye with warm water.

If you have any further questions on the use of ISOPTO PLAIN, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ISOPTO TEARS can cause side effects, although not everybody gets them.

- You may experience some or all of the following effects in your eye(s):
Blurred vision, eye pain, foreign body sensation in eyes, eye irritation, and redness.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of suspected side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE ISOPTO TEARS

Keep out of the reach and sight of children.

Do not refrigerate or store above 25° C.
Keep the bottle tightly closed.

Do not use the drops after the expiry date (marked 'Exp') on the bottle and the carton. The expiry date refers to the last day of that month.

Stop using the bottle 4 weeks after first opening, to prevent infections.

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

6. FURTHER INFORMATION

What ISOPTO TEARS contains

- The active ingredient is hypromellose (5 mg / 1 ml).
- The other ingredients are benzalkonium chloride, sodium citrate, disodium phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium chloride, purified water up to 1 mL

What ISOPTO TEARS looks like and contents of the pack

ISOPTO TEARS eye drops, solution comes in a container volume of 15 ml (droptainer).

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Alcon Pharmaceuticals Ltd., Rue Louis d`Affry 6, Case Postale, 1701 Fribourg, Switzerland

Manufacturer of the medicinal product

SA Alcon-Couvreur NV, Rijksweg 14, B-2870 Puurs, Belgium

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