Package Leaflet - Information for the User

TEARS NATURALE® SINGLE DOSE eye drops, solution

Dextran, Hypromellose

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to use TEARS NATURALE carefully to get the best results from it.

- **Keep this leaflet.** You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must **contact a doctor** if your symptoms worsen or do not improve after 3 days.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 WHAT TEARS NATURALE SINGLE DOSE IS AND WHAT IT IS USED FOR

TEARS NATURALE is a slightly viscous solution that acts as an artificial tear.

It is used to treat dry eyes caused by a lack of tears in the eye(s).

Replacement of the missing natural tears with an artificial tear helps to soothe and lubricate your eyes and provide relief from irritation.

2 BEFORE YOU USE TEARS NATURALE SINGLE DOSE

Do not use TEARS NATURALE...

If you are allergic to dextran 70, hypromellose or any of the other ingredients listed in section 6

If any of these apply, ask your doctor for advice.

Take special care ...

Only use TEARS NATURALE in your eye(s).

If you experience eye pain, headaches, changes in vision, persistent redness or irritation of your eyes, or if your condition worsens or does not improve within 3 days, stop using TEARS NATURALE and consult a doctor.

This medicine is available without a prescription. However, you still need to use TEARS NATURALE carefully to get the best results from it.

Pregnancy and breast-feeding

If you are pregnant or might get pregnant, or if you are breast-feeding a baby, **talk to your doctor** before you use TEARS NATURALE.

TEARS NATURALE can be used during pregnancy or breast-feeding.

Driving and using machines

You may experience blurred vision after using TEARS NATURALE. **Do not drive or use any machines unless your vision is normal.**

Using other medicines

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

If you are using more than one type of eye medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last.

Important information if you wear 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 USE TEARS NATURALE SINGLE DOSE

The usual dose

The usual dose is 1 or 2 drops in your eye(s) every one to two hours as required to relieve the irritation.

Always use TEARS NATURALE exactly as recommended. You should check with your doctor or pharmacist if you are not sure.

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HOW TO USE TEARS NATURALE SINGLE DOSE (continued)

How to use

- Wash your hands before you start.
- Open foil pouch and remove the plastic vial (picture 1).
- Twist off the cap of the plastic vial (picture 2).
- Hold the vial upside down.
- Tilt your head back.
- 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
- Bring the tip of the vial close to the eye. Do this in front of a mirror if it helps.
- **Do not touch your eye or eyelid**, surrounding areas or other surfaces with the tip of the vial. It could infect the drops.
- **Gently** squeeze the vial so that one drop falls into the gap between the eye and lower eyelid (picture 3).
- Now release the lower eyelid and keep closed for 2 minutes.
- If you use drops in both eyes, repeat the steps for your other eye. Dispose of vial after use. **Do not keep to use again.**
- If a drop misses your eye, try again.
- If you use more TEARS NATURALE than you should do not worry as it will not cause you any problems. If necessary TEARS NATURALE can be washed out of your eye with warm water.
- If you swallow TEARS NATURALE do not worry, it will not harm you.

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

4 POSSIBLE SIDE EFFECTS

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

You may experience some or all of the following effects in your eye(s):

Very common (affects more than 1 user in 10): blurred vision

Common (affects 1 to 10 users in 100): dryness, discomfort, abnormal sensation, feeling of something in the eye, eyelid problem

Uncommon (affects 1 to 10 users in 1,000): sensitivity to light, decreased sensation, itching, irritation, redness, itching, irritation.

Not known (cannot be estimated from the available data): pain, swelling, discharge, eyelid redness or crusting, increased tear production

You may also experience effects in other areas of your body including :

Uncommon: headache, discomfort (skin)

Not known: hypersensitivity

Reporting of 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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE TEARS NATURALE SINGLE DOSE

- Keep out of the reach and sight of children.
- Do not freeze or store above 25 °C.
- Do not use the drops after the expiry date (marked 'Exp') on the sachet and the carton. The expiry date refers to the last day of that month.
- Once the pouch has been opened, any unused vials should be stored in the opened pouch.
- Use all unopened vials within four days of opening the pouch.
- Dispose of the vial after use. **Do not keep an open vial to use again.**
- 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 TEARS NATURALE contains

- The active substances are dextran 70 1 mg/ml and hypromellose 3 mg/ml.
- The other ingredients are sodium chloride, potassium chloride, calcium chloride, magnesium chloride, zinc chloride, sodium hydrogen carbonate, carbon dioxide (to adjust pH) and purified water.

What TEARS NATURALE looks like and contents of the pack

TEARS NATURALE is a clear, colourless eye drops, solution supplied in a plastic single dose dispenser containing 0.4 ml. Four vials are enclosed in a foil overwrap. Each pack contains 28 vials.

The solution should not be used if it has changed colour or become cloudy.

TEARS NATURALE is suitable for people who are sensitive to preservatives.

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This leaflet was last revised in 01/2020

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