

Package Leaflet - Information for the User

TEARS NATURALE® eye drops, solution

(Dextran 70 0.1 % w /v, Hypromellose 0.3 % w /v)

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 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

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).

You should stop using the product and should consult a doctor if any of the following occur:

- You experience headache, eye pain, vision changes, irritation of the eyes, persistent redness
- Your eye condition gets worse
- Your eye symptoms persist for more than 3 days.

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 clear.**

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. There is a preservative in TEARS NATURALE (benzalkonium chloride) that can cause eye irritation and is also known to discolour soft contact lenses.

3 HOW TO USE TEARS NATURALE

The usual dose

The usual dose is 1 or 2 drops in your eye (s) as often as you require to relieve the irritation.

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

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

Only use TEARS NATURALE for dropping in your eye(s).

Do not use TEARS NATURALE if solution becomes cloudy or changes colour.

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HOW TO USE TEARS NATURALE (*continued*)

How to use

- Wash your hands before you start.
- Twist off the bottle cap.
- Hold the bottle pointing down, between your thumb and fingers.
- 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 (picture 1).
- Bring the bottle tip 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 dropper. It could infect the drops.
- **Gently press on the base** of the bottle to release one drop at a time (picture 2).
- **Do not squeeze the bottle**, only a gentle press on the bottom is needed.
- 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 use more TEARS NATURALE than you should** do not worry as it will not cause you any harm. If necessary TEARS NATURALE can be washed out of your eye with warm water. Do not put in any more drops until it is time for your next regular dose.
- If you swallow TEARS NATURALE do not worry, it will not harm you.
- If you forget to use TEARS NATURALE, continue with the next dose as planned. Do not use a double dose to make up.

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

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: allergy

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

HPRA Pharmacovigilance,
Earlsfort Terrace, IRL - Dublin 2

Tel : +353 1 6764971

Fax : +353 1 6762517

Website : www.hpra.ie

Email: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE TEARS NATURALE

- 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 TEARS NATURALE contains

- The active substances are dextran 70 0.1 % w/v and hypromellose 0.3 % w/v.
- The other ingredients are disodium edetate, sodium chloride, potassium chloride, benzalkonium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water.

What TEARS NATURALE looks like and contents of the pack

TEARS NATURALE is a clear, colourless liquid supplied in a pack containing a 15 ml plastic bottle with a screw cap.

Marketing authorisation holder:

Alcon Laboratories Ireland Limited
Cork Business & Technology Park
Model Farm Road
Cork
Co Cork

Manufacturer:

Alcon Laboratories Belgium
Lichterveld 3
2870 Puurs-Sint-Amands
Belgium

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Alcon