

PACKAGE LEAFLET: INFORMATION FOR THE USER



Clear Eyes Eye Drops Solution

Hamamelis Water 12.5% v/v

Naphazoline Hydrochloride 0.01% w/v

Removes redness fast and soothes sore eyes

- Read all of this leaflet carefully before you start using Optrex Clear Eyes Eye Drops as it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see Section 4).
- You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

What is in this leaflet

1. What Optrex Clear Eyes Eye Drops are and what are they used for
2. What you need to know before you use Optrex Clear Eyes Eye Drops
3. How to use Optrex Clear Eyes Eye Drops
4. Possible side effects
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6. Contents of the pack and other information

1. What Optrex Clear Eyes Eye Drops are and what they are used for

Optrex Clear Eyes Eye Drops are an eye drop solution. They are used to

- Relieve redness
- Soothe irritation

Caused by the day to day effects of modern living such as dusty, smoky atmospheres, eye strain and chlorine in swimming pools.

2. What you need to know before you use Optrex Clear Eyes Eye Drops

Do not use this product if you

- are allergic or sensitive to hamamelis water, naphazoline or any of the ingredients listed in section 6
- suffer from closed-angle glaucoma, other eye disease or have had eye surgery
- are under 12 years old
- are taking monamine oxidase inhibitors (MAOIs), or within 14 days of stopping such medicine

Warnings and precautions

- for external use only
- if there is no improvement after 24 hours, your symptoms get worse or you get new symptoms (such as eye pain, changes in vision), stop using this product and seek advice from your doctor or pharmacist
- if you are being treated for high blood pressure, arteriosclerosis, cardiovascular disease, depression, heart disease, diabetes or increased thyroid activity, consult your doctor before using the drops

Other medicines and Optrex Clear Eyes Eye Drops

Talk to your doctor before using this product if you

- are taking medicines for high blood pressure, heart disease or diabetes
- are taking medicines for thyroid disorders
- are taking digoxin (for heart disorders) or quinidine (for malaria)
- are taking medicines for depression particularly tricyclic antidepressants
- have taken monoamine oxidase inhibitors (MAOIs) for depression within the last 14 days
- are taking medicines to treat glaucoma
- are taking tricyclic antidepressants

Pregnancy, breast-feeding and fertility

- If you are pregnant or planning to become pregnant, speak to your doctor or pharmacist.
- This product can be used while breast-feeding

Driving and using machines

Do not drive or operate machinery if vision is blurred

Important information about some of the ingredients in Optrex Clear Eyes Eye Drops

This medicine contains 0.0025 mg benzalkonium chloride in each drop.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Optrex Clear Eyes Eye Drops

For adults and children over 12 years. Use no more than 4 times a day

- For external use only. Use only as directed
- Do not use on children under 12 years

Applying the drops

1. Check the seal is not broken before first use
2. Wash and dry your hands
3. Remove plastic cap from the eye drop tip
4. Gently pull the lower lid downward and tilt your head back
5. Squeeze the bottle gently and apply 1-2 drops into the pocket formed by your lower lid, but don't allow the tip to touch your eye or the other surfaces of the eye
6. Repeat for the other eye
7. Replace the cap straight away
8. Some people prefer to apply drops this way: Close the eye. Apply one or two drops to the inner corner of your eye. Open your eye and blink several times to spread the drops properly

**Whilst using**

- This product is intended for occasional use and should not be used for more than 72 hours.
- Any discomfort after using the drops will quickly disappear.
- **Stop** using and consult a doctor or pharmacist if your symptoms get worse (increased redness) or you have new symptoms (eye pain, stinging, irritation, changes in vision).
- Using substantially more drops than the recommended dose, or if Optrex Clear Eyes Eye Drops is accidentally swallowed, more severe side effects may occur. These symptoms may include decreased heart rate (bradycardia), severe headache, nausea, vomiting, problems with breathing, increased heart rate (tachycardia), and chest pain.
- If you experience side effects, or in cases of accidental intake/ingestion or overdose, seek immediate medical attention.

Length of treatment

If there is no improvement after **24 hours**, stop using and consult a doctor or pharmacist. Using the drops for longer periods may increase redness of the eye.

4. Possible side effects

Side effects are very rare. A few people may have an allergic reaction to the ingredient. Headache, dizziness, nausea, eye pain, eye irritation and stinging may occur. If anything unusual happens or if you are concerned about the effects of these drops, talk to your pharmacist or doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance Website: www.hpra.ie By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Optrex Clear Eyes Eye Drops

Keep all medicines out of the sight and reach of children.

Do not store above 25°C.

You must throw away unused drops 28 days after first opening the bottle or sooner if the contents change colour or become cloudy. The preservative can only keep them sterile in use for a limited time. Also, do not use them after the expiry date (printed on the dropper bottle and the carton).

6. Contents of the pack and other information**What Optrex Clear Eyes Eye Drops contains**

Optrex Clear Eyes Eye Drops contain hamamelis water (as distilled witch hazel 12.5% v/v) and naphazoline hydrochloride 0.01% w/v as the active ingredients. Also contains ethanol (as constituent of distilled witch hazel), purified water, glycerol, borax, boric acid, disodium edetate, benzalkonium chloride, hydrochloric acid, sodium hydroxide.

What Optrex Clear Eyes Eye Drops look like and contents of the pack

Optrex Clear Eyes Eye Drops is a colourless, clear or practically clear solution, practically free from particles. The pack contains 10ml of Optrex Clear Eyes Eye Drops.

Marketing Authorisation Holder and Manufacturers

PA Holder: Optrex Ltd., 103-105 Bath Road, Slough, Berkshire, LS1 3UH. UK. PA 275/2/1 Manufacturers: RB Healthcare International Ltd, Nottingham, NG90 2DB, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

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