

Patient Information leaflet (PIL)

1. What AUROFORT is and what it is used for

AUROFORT belongs to a group of medicines known as steroidal anti-inflammatory drugs. AUROFORT is used in adults for the short-term treatment of eye inflammation.

It reduces the irritation, burning, redness and swelling of eye inflammation caused by chemicals, heat, radiation, allergy, or foreign objects in the eye.

2. What you need to know before you use AUROFORT

Do not use AUROFORT

- If you are allergic to prednisolone acetate, benzalkonium chloride or any of the other ingredients of this medicine (listed in section 6)
- If you suffer from viral, fungal or bacterial eye infections
- If you suffer from tuberculosis of the eye
- If you have injuries to or ulcers on the cornea
- If you have previously had herpes simplex

Warnings and precautions

Talk to your doctor before using AUROFORT if you suffer from, or have in the past suffered from:

- Eye ulcers or have had a disease or treatment to the eye that caused the tissue to become thin
- You have glaucoma or are being treated for raised pressure within the eye
- You have had surgery for cataracts
- Bacterial, viral or fungal eye infections

Contact your doctor if you experience blurred vision or other visual disturbances.

Children

Do not give to a child less than 12 years old as this medicine contains boron and may impair fertility in the future.

Tell your doctor before using AUROFORT, if you are:

Using or have used other steroid eye drops, as frequent or long-term use of steroids can result in additional side effects.

Other medicines and Aurofort

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

Some medicines may increase the effects of AUROFORT and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine as steroids may be harmful to the baby.

Driving and using machines

AUROFORT may cause temporary blurred vision. Do not drive or use machinery until the symptoms have cleared.

AUROFORT contains benzalkonium chloride

This medicine contains 0.06 mg benzalkonium chloride in each 1 ml.

Contact lenses

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 AUROFORT

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 or 2 drops into the affected eye(s) 2 to 4 times a day. During the first two days of treatment you may be asked to apply the drops as often as every hour.

Instructions for use

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

Apply your eye drops in the following way:

1. Wash your hands. Shake the bottle well before use. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small pocket.
3. Turn the bottle upside down and squeeze it to release one or two drops into each eye that needs treatment.
4. Let go of the lower lid, and close your eye. Press your finger against the corner of your eye (the side where your eye meets your nose) for one minute.

If a drop misses your eye, try again.

To avoid eye injury and contamination, do not let the tip of the dropper touch your eye or anything else.

Replace and tighten the cap straight after use.

Wipe off any excess liquid from your cheek with a clean tissue.

If you use this medicine for more than 10 days, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you. Your doctor will check your eyes for:

- an increase in pressure
- cataracts
- infection

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

If you use more AUROFORT than you should

Putting too many drops in your eye(s) is unlikely to lead to unwanted side effects. If you have placed too many drops in your eye(s), wash your eye(s) with clean water. Apply your next dose at the normal time.

If, by accident, anyone drinks this medicine, contact your doctor straight away.

If you forget to use AUROFORT

If you forget a dose apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose. Then apply your next dose as usual and continue with your normal routine.

Do not take a double dose to make up for a forgotten dose.

If you stop using AUROFORT

AUROFORT should be used as advised by your doctor. Do not stop using AUROFORT until your doctor has told you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should see your doctor immediately if you experience:

- ulcers on the surface of the eye
- severe pain in the eye

You should see your doctor if any of the following effects prove troublesome or if they are long-lasting:

- allergic reaction
- headache
- increased pressure within the eye
- centre of the eye becomes cloudy (cataracts)
- a feeling that something is in your eye
- eye infections (bacterial, fungal or viral)
- mild stinging or irritation
- red eye
- blurred or poor vision
- pupil dilation
- change in sense of taste
- rash or itching

5. How to store AUROFORT

Keep this medicine out of the sight and reach of children.

Use the solution within the one month after opening the container

Do not use this medicine after the expiry date which is stated on the bottle label and the bottom of the carton after EXP. The expiry date refers to the last day of that month for an unopened bottle.

Store below 30°C.

Do not use this medicine if you notice the tamper-proof seal is broken.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What AUROFORT contains

- The active substance is Prednisolone acetate 1.0% w/v.
- The other ingredients are benzalkonium chloride, EDTA disodium salt, hydroxyl propyl methyl cellulose, sodium citrate, sodium chloride and purified water.

What AUROFORT looks like and contents of the pack

5ml filled in 10ml Low density polyethylene container with HDPE cap and Nozzle. Such 10ml is packed in a monocarton with package insert.

Marketing Authorisation Holder

Aurolab, No.1,
Sivagangai Main road,
Veerapanjan,
Madurai - 625020,
India.

Manufacturer

Aurolab, No.1,
Sivagangai Main road,
Veerapanjan,
Madurai - 625020,
India.