

Package leaflet: Information for the user

Ultracortenol 5 mg/g eye ointment prednisolone pivalate

Read all of this leaflet carefully before you start using 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. See section 4.

This leaflet contains information on the following:

1. What Ultracortenol is and what it is used for
2. What you need to know before using Ultracortenol
3. How to use Ultracortenol
4. Possible side effects
5. How to store Ultracortenol
6. Contents of the pack and other information

1. What Ultracortenol is and what it is used for

Ultracortenol is used in adults to treat:

A severe inflammation in the anterior part of the eye that has not occurred due to an infection.

Ultracortenol contains the active substance Prednisolone pivalate.

Prednisolone pivalate is a glucocorticoid (a steroid) with a strong anti-inflammatory effect. It inhibits the release of inflammatory substances in the body, thereby preventing signs of inflammation, e.g. swelling, dilation of blood vessels and scarring.

2. What you need to know before you use Ultracortenol

Do not use Ultracortenol:

- If you are allergic to the active substance Prednisolone pivalate, other glucocorticoids or any of the other ingredients of this medicine (listed in Section 6).
- If you have an eye infection caused by herpes virus (dendritic keratitis) or any other viral infection in the eye.
- If you have an untreated bacterial or fungal infection in the eye.
- If you have Narrow-angle glaucoma or advanced glaucoma and only medication does not provide sufficiently good effect.

Warnings and precautions

Talk to your doctor or pharmacist before using Ultracortenol if you:

- Have or have had eye ulcers or thinning of the eye tissue as a result of disease or eye treatment.
- If you have been operated for the clouding of the lens (cataract).
- Have or have had eye infections caused by bacteria, viruses (e.g. herpes virus) or fungi.
- If you have glaucoma or if you are being treated for increased pressure in the eye.
- If you have recently used or are using any other eye medicine containing glucocorticoids. Frequent or prolonged use of glucocorticoids can cause additional side effects.

Other medicines and Ultracortenol

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

No effects on other drugs have been reported.

If, in addition to Ultracortenol, you need to use other eye medicines that can increase the pressure in the eye, this side effect may be stronger.

Pregnancy and breast-feeding

Pregnancy

It is unknown whether the fetus can be affected. If you are pregnant, think you may be pregnant, or are planning to have a baby, consult a doctor or pharmacist before using this medicine.

Breast-feeding

Ultracortenol passes into mother's milk, but probably does not affect breast-feeding children. Ultracortenol can be used during breastfeeding.

Driving and using machines

Ultracortenol can cause temporary blurred vision. Wait until this side effect has passed before driving or using machines.

Ultracortenol contains wool fat and cetostearyl alcohol

Wool fat and cetostearyl alcohol may cause local skin irritation (e.g. contact dermatitis).

3. How to use Ultracortenol

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

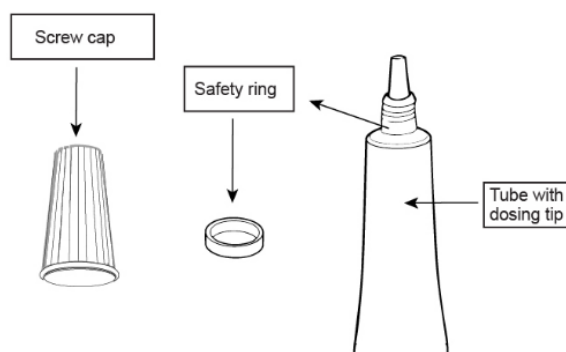
The recommended dose is:

Unless otherwise prescribed by the doctor, a string of 3-5 mm ointment should be applied 2-4 times daily in the affected eye. The maximum daily dose of ointment is a string of 5 mm, 4 times daily.

The duration of treatment is determined by your doctor. If symptoms have not subsided after 2 days, consult your doctor. If you need to be treated for more than 10 days, your ophthalmologist must regularly check your cornea and eye / eyes pressure.

Use should then be slowly reduced over the following days and weeks.

How to open tube:



1. The tube is sealed and has a safety ring around the neck of the tube, the first time you use it.
2. Before using the tube for the first time, unscrew the cap and dosing tip and remove the safety ring.
3. Screw back the dosing tip to the tube to perforate the sealing of the tube.
4. The tube is now ready for use.
5. Carefully squeeze out the contents of the tube.

Do not use the medicine if it does not have the ring and talk to your pharmacist.

Instructions on Use

- Do not use the tube content if the safety cover on the tube is damaged before the first opening.
- Wash your hands.
- To prevent contamination of the drug and injury, make sure that the dosing tip does not touch the eye, the eyelid or the area around the eye or any other objects.
- Contact lenses must be removed prior to application and must not be inserted until after at least 15 minutes after application of the ointment.
- Lean your head back.
- Take the opened tube in one hand and gently pull down the lower eyelid with the index finger of your other hand to form a pocket between your eyelid and eye.
- Hold the tip of the tube close to the eye.
- Gently press the tube to place about 3 to 5 mm long line of ointment in the pocket.
- After flashing 2-3 times, the ointment will form a thin layer over the eye.
- If both eyes are to be treated, repeat the procedure for the second eye.
- Close the tube immediately after use to avoid contamination.
- If you are using any other medicine to be applied to eye, allow it to pass for at least 5 minutes between each medicine.
- Eye ointment should be applied at last, if multiple eye products are to be used.
- Close your eye and press onto the corner of your eye beside the nose for a minute. Please immediately clean excess overflow from the face. This prevents Ultracortenol from passing into the rest of the body via the tear duct and the skin.

If you use more Ultracortenol than you should

If you have placed too much ointment in the eye(s), it is unlikely to cause side effects. Blink a few times so that the ointment ends up on the eyelashes and then gently wipe it away.

If you forget to use Ultracortenol

If you forget to use Ultracortenol, use it as soon as possible. Then proceed with the usual dosage. If Ultracortenol is not used regularly or you often forget to use it, treatment may be less effective.

If you stop using Ultracortenol

Use Ultracortenol regularly as prescribed by your doctor. Use Ultracortenol during the period prescribed by your doctor.

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.

If you experience eye pain, you should contact your doctor immediately as it may be due to ulcers on the cornea or eye surface. This is rare (may affect up to 1 in 1000 people).

Other side effects that may occur:

Common (may affect up to 1 in 10 people):

Increased pressure in the eye/eyes during prolonged treatment, burning sensation, tingling, eye irritation, the feeling of having something in the eye.

Uncommon (may affect up to 1 in 100 people): Blurred vision

Rare (may affect up to 1 in 1000 people): Allergic reactions in the eye/eyes, clouding of the eye lens (cataract).

Not known: frequency cannot be estimated from the available data: hypersensitivity, hives, headache, pupil dilation, rash or itching, impaired sense of taste, eye infection caused by bacteria, fungus or viruses.

The following side effects have been seen with other glucocorticoids used in the eyes:

Rare (may affect up to 1 in 1000): eye inflammation, drooping eyelids, difficulty focusing.

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 [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ultracortenol

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Do not use this medicine if you notice that the seal of the tube is damaged.

Use within 4 weeks after first opening.

Do not throw away any medicines via 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 Ultracortenol contains

The active substance is prednisolone pivalate

1 g of ointment contains 5 mg of prednisolone pivalate.

1 cm string of ointment contains approx. 0.1 mg prednisolone pivalate.

The other ingredients are:

cetostearyl alcohol; wool fat; paraffin, white soft; paraffin, liquid and water, purified.

What Ultracortenol looks like and contents of the pack

5 g white to slightly yellowish, odourless ointment in an epoxy-phenol coated sealed aluminium tube with white HDPE canula tip and white HDPE screw cap.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

This leaflet was last revised 5 Feb 2026