

Ultracortenol 0.5% - Eye drops

Active substance: Prednisolone acetate

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.

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1. What Ultracortenol 0.5% - Eye drops is and what it is used for
2. What you need to know before you use Ultracortenol 0.5% - Eye drops
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1. What Ultracortenol 0.5% - Eye drops is and what it is used for?

Ultracortenol 0.5% - Eye drops is an ophthalmic drug with the active substance Prednisolone acetate. The active substance Prednisolone belongs to the group of glucocorticoids (Cortisone).

Ultracortenol 0.5% - Eye drops is used for treating inflammations and allergies:

- Non-infectious allergic conjunctivitis
 - Conjunctivitis in spring (Conjunctivitis vernalis)
 - Non-infectious keratitis
 - Inflammation of the uvea, iris or ciliary body (Uveitis, Iritis and Iridocyclitis)
- Ultracortenol 0.5% - Eye drops is not suitable for the treatment of eye infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ULTRACORTENOL 0.5% - EYE DROPS

Do not use Ultracortenol 0.5% - Eye drops:

- if you are allergic to the active substance (Prednisolone acetate) or any of the other ingredients of this medicine (listed in section 6).
- in the case of injuries or ulcers of the corneal
- if you have an eye infection (caused by bacteria, viruses, fungi or tuberculosis)
- if you have an increase in intraocular pressure (glaucoma, glaucoma)
- if you are a so-called „cortisone responder“ (increase in intraocular pressure in response to corticosteroids)

Warnings and precautions

Talk to your doctor or pharmacist before using Ultracortenol 0.5% - Eye drops.

- If you have a red eye which is not diagnosed by the doctor, you should not use Ultracortenol 0.5% eye drops.
- If you have severe allergic conjunctivitis that does not respond to standard treatment. Use Ultracortenol 0.5% eye drops for short time only.
- If blurred vision or other visual disorders occur, you should consult your doctor.
- In susceptible patients, prolonged treatment may result in increased intra ocular pressure and/or cataract formation (clouding of lens/cataract). Corticosteroid containing eye drops should only be used for more than 10 days, if there is strict surveillance by an ophthalmologist who perform periodic examination of intra ocular pressure and cornea.
- Caution is advised in diabetic patients, as they are prone to increased intra ocular pressure and/or cataract. Please inform your ophthalmologist, if you are diabetic.
- There are reports of cataract formation after long term treatment with topical corticosteroids.
- Long term treatment with topically applied corticosteroids may lead to penetrating eye injuries (perforations) in patients with disease-induced thinning of the cornea or the dermis, the so called "white eye skin".
- Before treatment with Ultracortenol 0.5% eye drops it must be ensure that the eye is not infected.
- Due to inhibitory effect on the immune system, a later infection may occur in the treatment of non-infectious inflammation with Ultracortenol 0.5% eye drops. There is also the possibility of obscuring or aggravating an existing bacterial infection without adequate treatment with suitable antibiotics. Acute purulent infections can be obscured or exacerbated by use of corticosteroids.
- The use of corticosteroid may lead to exacerbation or onset of a viral eye infection (including herpes simplex). The use of corticosteroid containing eye drops should therefore be carefully monitored in patients who have had herpes simplex infection in the past.
- Fungal infections of the cornea often occur simultaneously with long term treatment with local corticosteroids. Therefore, the possibility of fungal infections in patients with persistent corneal ulcers should be considered. Corticosteroids containing ophthalmic drugs delay wound healing especially in long term treatment and high doses.
- The use of corticosteroid after cataract operation may delay healing and increase the likelihood of blistering.
- As with other eye drops, the use of Ultracortenol 0.5% eye drops while wearing contact lenses is not recommended. Contact lenses should be removed before use and reinserted at least 15 minutes after application. Basically contact lenses should only be worn during treatment, if disease allows it.

Other medicines and Ultracortenol 0.5% - Eye drops

Please tell your doctor or pharmacist if you are using, have recently used any other medicines even medicines obtained without prescription.

Some medicines may increase the effect of Ultracortenol 0.5% eye drops and your doctor may monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

If you are using some eye preparations that dilate your pupil, some patients are at increased risk of elevating intra ocular pressure.

The use of Ultracortenol 0.5% eye drops together with green star medicines may increase your intraocular pressure and reduce effectiveness of drug against increased intraocular pressure.

The concomitant topical use of corticosteroids and nonsteroidal anti-inflammatory agents in the eye may increase the risk of corneal complications in patients with existing severe corneal inflammation.

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.

Pregnancy

There is insufficient data for the use of Ultracortenol 0.5% - Eye drops during pregnancy.

As absorption of the active substance into the bloodstream is to be expected even when using Ultracortenol 0.5% - Eye drops on the eye and thus adverse effects for the unborn child can not be ruled out, Ultracortenol 0.5% - Eye drops may be used during pregnancy only after thorough risk-benefit analysis of the doctor in charge.

Please consider that by pressing a finger on the nasolacrimal canal the absorption of the active substance into the bloodstream is reduced. Nevertheless the lowest therapeutic effective dosage should be used and especially a long term use should be avoided.

Breast-feeding

The active substance in Ultracortenol 0.5% - Eye drops passes over into the breast milk. In case of higher dosages or long term use the baby should be weaned.

Driving and using machines

After applying Ultracortenol 0.5% eye drops, mild, temporary eye irritation may affect your eyesight. It is unlikely that your vision will be greatly impaired. However, these temporary effects can make you feel blurry for a short time. Please wait until these effects have passed before you drive or operate machinery.

Ultracortenol contains benzalkonium chloride

Benzalkonium chloride can cause eye irritation. Contact with soft contact lenses should be avoided. Benzalkonium chloride can lead to discoloration of soft contact lenses. You must remove contact lenses before use and reuse them at the earliest 15 minutes after use.

3. How to use Ultracortenol 0.5% - Eye drops

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

Unless otherwise prescribed by the doctor, the recommended dose is 1-2 drops 2 to 4 times daily in the affected eye.

In case of severe inflammation, the drops may be applied hourly during the first 24-48 hours or as prescribed by the treating physician. The intervals between applications may be lengthened with the onset of symptoms.

Type of administration

For ocular administration.

Add drop wise to the conjunctival sac of the affected eye with slightly bent back head. Shake before use. When using eye drops you should always avoid touching the tip of the bottle with eye or skin.

How to use Ultracortenol 0.5% eye drops

1. Wash your hands.
2. Take a clean cloth and wipe gently around your eyes to remove any moisture present (Figure 1).
3. Unscrew the vial and check that the dropper is clean.

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4. Tilt your head back slightly, pulling your lower eyelid down slightly (Figure 2) and
5. Drop one drop into the center of your lower eyelid (Figure 3). Do not touch your eye with the bottle tip.
6. Release your lower eyelid and gently press the inner corner of the treated eye against your nose bridge (Figure 4). Blink a few times while maintaining pressure to distribute the drop over the surface of your eye.
7. Remove any excess eye drop fluid by dabbing.
8. Repeat these steps for the other eye as needed.

Figure 1



Figure 2



Figure 3



Figure 4



The uptake of the drug into the bloodstream can be reduced by gently pressing the naso-lacrimal duct with the finger or by holding the eyelids closed for 3 minutes after the application of Ultracortenol 0.5% eye drops. Reducing the uptake of the drug into the bloodstream can reduce the likelihood of adverse side effects and increase local potency.

Contact lenses should be removed before use and should not be reinserted until 15 minutes after application.

If more than one drug is used on the eye, there must be a minimum of 15 minutes between 2 applications.

Length of administration

The duration of the application depends on the desired effect, the severity of the inflammation and the patient's response and should be decided by the treating physician.

The treatment usually takes a few days to a maximum of 14 days. If you use Ultracortenol 0.5% eye drops for more than 10 days, your ophthalmologist must regularly measure your intraocular pressure and check the condition of your cornea.

Please do not stop treatment abruptly. The dosage should be reduced slowly over several days. If your symptoms do not improve after 2 days of treatment, consult your ophthalmologist.

If you have the impression that the effect of Ultracortenol 0.5% eye drops is too strong or too weak, talk to your doctor or pharmacist.

Use in children and adolescents

Use in these age brackets is not recommended because of insufficient data on safety and efficacy.

If you use more Ultracortenol 0.5% - Eye drops than you should

You do not have to take any special measures. There are no cases of overdose known. If you are worried, contact your doctor.

If too many drops are inadvertently brought into the eye, the excess amount will generally flow down the nose. In case of accidental ingestion of the eye drops, please contact your doctor.

If you forget to use Ultracortenol 0.5% - Eye drops

Do not take the double dose to make up for the forgotten application. Once the application is forgotten, get it as soon as possible and then return to your usual dosing schedule.

If you stop using Ultracortenol 0.5% - Eye drops

Please follow the instructions for use or Ultracortenol 0.5% - Eye drops may not have the intended efficacy. The dosage of Ultracortenol 0.5% - eye drops can be reduced, but the treatment should not be stopped prematurely or abruptly.

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.

After use of Ultracortenol 0.5% - Eye drops temporary burning and stinging of the eyes or other minor ailments of eye irritations (e.g. blurry vision, foreign body sensation, allergic reactions) may occur but this doesn't affect the success of the treatment.

Rarely (can affect up to 1 in 100 people):

- Blurred vision

Very rare (may affect up to 1 in 10,000 people):

- hypersensitivity, hives
- headache
- increased intraocular pressure, cataract, penetrating eye injury (scleral or corneal perforation), fungal infection of the eye, viral eye inflammation, eye irritation, pupil dilation, drooping upper eyelid (ptosis), damage to the cornea caused by disorder of the restoration
- disruption of the taste sensation
- itching, rash

In addition, corticosteroid-containing eye drops such as Ultracortenol 0.5% eye drops may cause the following side effects:

- inflammation of the middle eye skin (acute anterior uveitis iritis)
- corneal inflammation (keratitis)
- conjunctivitis
- corneal ulcers
- conjunctival irritation
- loss of close-up of the lens (loss of accommodation)
- hanging upper eyelid (ptosis)

If you experience any of the above mentioned side effects, please contact your doctor directly.

If you notice a bitter taste after using Ultracortenol 0.5% eye drops, you can neutralize it with a non-alcoholic beverage (for example, juice, milk).

Report of side effects

If you notice any side effects, consult your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly through the national reporting system:

Bundesamt für Sicherheit im Gesundheitswesen, Traisengasse 5, 1200 Vienna, Fax: +43 (0) 50 555 36207, Website: <https://www.basg.gv.at>

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

5. How to store Ultracortenol 0.5% - Eye drops

Do not store above 25°C. Store in the original packaging in order to protect from light.

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

You may take the medicine according to the instructions given on the carton/container. Do not use this medicine after the expiry date which is stated on the carton/label after "EXP". The expiry date refers to the last day of that month.

After opening, the medication may only be used for 4 weeks at the longest.

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 to protect the environment.

6. Contents of the pack and other information

What Ultracortenol 0.5% - Eye drops contains

The active substance is Prednisolone acetate

1 ml eye drop suspension contains 5 mg Prednisolone acetate. 1 drop is equivalent to ca. 0.025 ml.

The other excipients are: benzalkonium chloride (preservative), sodium dihydrogen phosphate [$2H_2O$], sodium monohydrogen phosphate [$12H_2O$], sodium chloride, water for injection.

What Ultracortenol 0.5% - Eye drops looks like and contents of the pack

Plastic dispenser bottle (LDPE) with 5 ml content. White plastic screw cap (HDPE), tamper evident.

After shaking: white to almost white cloudy odourless suspension

Marketing Authorisation Holder and Manufacturer

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MA no.: 10319

This leaflet was last revised in April 2017.