

Package leaflet: Information for the user

HYDROCORTISON CUM CHLORAMPHENICOL 5 mg/g + 2 mg/g eye ointment

hydrocortisone acetate, chloramphenicol

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.

What is in this leaflet

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

1. What Hydrocortison cum Chloramphenicol is and what it is used for

Hydrocortison cum Chloramphenicol eye ointment is a combined medicinal product consisting of an anti-infectious component, the broad-spectrum antibiotic chloramphenicol, and an anti-inflammatory component, the synthetic corticosteroid hydrocortisone.

Chloramphenicol destroys a large number of infectious agents by inhibiting the production of proteins in their cells, thus favourably influencing ocular infections.

Hydrocortisone has anti-inflammatory, anti-oedematous and anti-allergic action. It suppresses the inflammatory reaction of the body against agents of mechanical, chemical or immunological nature.

Hydrocortison cum Chloramphenicol eye ointment is used in superficial inflammatory conditions of the eyelid, conjunctiva, cornea and anterior segment of the eye, where the use of

a corticosteroid is recommended and there is a risk of developing or an existing bacterial infection caused by chloramphenicol-susceptible microorganisms:

- Inflammatory conditions of the palpebral and ocular conjunctiva (conjunctivitis), cornea (keratitis) and anterior segment of the eye;
- Chronic anterior uveitis (inflammation of the vascular coat of the eye).

2. What you need to know before you use Hydrocortison cum Chloramphenicol

Do not use Hydrocortison cum Chloramphenicol

- if you are allergic to chloramphenicol, hydrocortisone or any of the other ingredients of this medicine (listed in section 6).
- if you have a herpetic infection of the cornea, viral diseases of the cornea and conjunctiva;
- in corneal ulcers;
- in mycobacterial ocular infections;
- in trachoma (a chronic inflammatory disease of the conjunctiva and cornea caused by Chlamydia);
- if you have an eye infection caused by fungi;
- in conditions with depressed bone marrow function (myelopathy, aplastic anaemia).

Warnings and precautions

A hypersensitivity reaction to any of the ingredients of the product may develop, presenting with itching of the eyelid, swelling and redness of the conjunctiva, which may require discontinuation of the treatment with this product.

Prolonged use of corticosteroids may cause increased intraocular pressure resulting in a damage to the optic nerve and defects in vision. Therefore, regular control of the intraocular pressure is required, especially during prolonged use and in susceptible patients (diabetes, glaucoma, a family history of glaucoma).

Frequent and prolonged use of corticosteroids may lead to the occurrence of posterior subcapsular cataract (a type of clouding of the eye's lens).

In children and adolescents under 18 years of age, the treatment should be limited to the shortest time possible. Prolonged use of corticosteroids may cause suppression of the function of certain endocrine glands (the hypothalamus, pituitary gland, adrenal gland) in the body of the child.

Prolonged use may suppress the defensive response of the body and thereby increase the risk of development of secondary ocular infections.

In acute suppurative inflammations of the eye, corticosteroids may mask or activate the existing infection.

In conditions that cause thinning of the cornea or sclera, the use of topical corticosteroids may result in a perforation (a breakdown of the eye).

Prolonged use of antibiotics may cause the development of non-susceptible microorganisms, including fungi. In the case of superinfection, appropriate therapy should be instituted.

Prolonged treatment with topical chloramphenicol may cause very rarely suppression of the bone marrow function.

Application of eye ointments may slow down the healing of corneal wounds.

During the treatment with this product, wearing contact lenses is not advisable.

Other medicines and Hydrocortison cum Chloramphenicol

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

Co-administration of anticholinergic agents (atropine) may lead to increased intraocular pressure. Co-administration of medicines that suppress the haematopoietic function may potentiate the damaging effect of chloramphenicol on the bone marrow.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

There are no data of foetal harm in pregnant women; however, the use of the product may be considered only if clearly needed and after careful evaluation of the benefit/risk ratio.

Breast-feeding

The use of the product is not recommended during breast-feeding, because of a possible accumulation of chloramphenicol and, hence, damage to the blood formation due to the imperfect metabolism of the infant.

Driving and using machines

As with all products for ocular use, transient blurring of vision or other disturbances may influence the ability to drive and use machines. After applying Hydrocortison cum Chloramphenicol, you should wait until your vision clears, before you start operating machines or driving.

Hydrocortison cum Chloramphenicol contains wool fat (lanolin), propyl parahydroxybenzoate, methyl parahydroxybenzoate

In its composition, Hydrocortison cum Chloramphenicol eye ointment contains wool fat (lanolin), which may cause a local skin reaction (for example, contact dermatitis).

In its composition, Hydrocortison cum Chloramphenicol eye ointment contains propyl parahydroxybenzoate and methyl parahydroxybenzoate, which may cause allergic reactions (possibly, of a delayed type) and very rarely, bronchospasm.

It is important to know that you should not wear contact lenses in the presence of an eye infection and during the treatment with the product.

3. How to use Hydrocortison cum Chloramphenicol

Always use Hydrocortison cum Chloramphenicol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Medicinal product subject to medical prescription. For topical use only.

Usually, the ointment is applied 1 - 3 times daily, depending on the severity of disease.

It is more appropriate to use eye drops during the day and an eye ointment during the night.

The dosage and duration of the treatment are determined by the attending physician.

The treatment continues until the signs of the disease resolve (5-7 days on the average), but not more than 14 days.

It is necessary to make a periodic assessment of the bacterial response to the ongoing treatment.

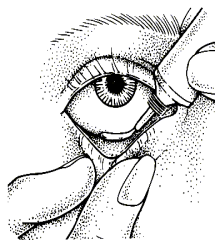
Use in children: The efficacy and safety have not been established in children less than 3 years of age.

When co-administered with other product for ocular use, the interval between the applications of the two products should be at least 10 minutes, as the eye ointment should be applied last.

Keeping hygiene during the application of the eye ointment and avoiding the contact between the tip of the tube and the eye or surrounding objects are of importance, since the tip may be contaminated, thus leading to development of an eye infection with serious consequences to the eye, even a loss of vision. Always wash your hands before handling the tube!

If you think that your tube is contaminated, contact your doctor before proceed with the use of this eye ointment.

Instructions for use



1. Before using the tube for the first time, make sure that the protective strip between the cap and the tube is not broken. Wash your hands and twist off the cap.
2. Hold the tube between your thumb and forefinger, as close as possible to your eyelid, without touching it.
3. Tilt your head slightly forward and pull the lower eyelid away from the eye to form a pouch between the eyelid and the eye. The strip of the eye ointment will fall right here.
4. Pay attention not to touch the tip of the tube to the eye, eyelid or adjacent surfaces. Squeeze carefully a strip of the ointment with length of about 1-1.5 cm, in a way to fall into the formed pouch of the lower eyelid.
5. After applying Hydrocortison cum Chloramphenicol, close the eyelid gently for 1 - 2 minutes and rotate the eyeball in all directions, to enable the spread of the ointment on the entire ocular surface.
6. Using a clean tissue, remove the excessive amount of the ointment from the eyelid or eyelashes. Using another clean tissue, wipe the tip of the tube and close it tightly with the cap.
7. If it is necessary to apply the eye ointment in both eyes, repeat all previously described steps for the other eye.

Use this tube of Hydrocortison cum Chloramphenicol for your eyes only!

If you use more Hydrocortison cum Chloramphenicol than you should

Do not apply the medicine more frequently or for a longer time than directed by your doctor, in order to avoid overdose. If however you have accidentally used more than the dose prescribed, contact your doctor or pharmacist, although it is usually sufficient to wash the eye thoroughly with lukewarm water.

Overdose and toxicity are unlikely to occur with the topical use of the product, when adhering strictly to the instructions for use.

The clinically presented symptoms of overdose with Hydrocortisone cum Chloramphenicol eye ointment are similar to the side effects: redness, tearing, swelling and itching of the eyelid.

If you forget to use Hydrocortison cum Chloramphenicol

Do not use more than the amount needed to make up for a missed application. Apply the usual dose as soon as you remember and continue the treatment as usual.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Hydrocortison cum Chloramphenicol can cause side effects, although not everybody gets them.

The side effects related with the action of the combined medicinal product Chloramphenicol hydrocortisone eye ointment can be attributed to the antibiotic component, to the corticosteroid component or to the action of the combination itself.

The most common side effects related with the local ophthalmic use of chloramphenicol include the development of hypersensitivity and the occurrence of ocular irritation, manifested by itching, swelling of the eyelids and redness of the conjunctiva.

Although very rarely, suppression of the bone marrow function and development of aplastic anaemia (a severe reduction in the number of blood cells resulting in weakness, bruising or an increased risk of infections) may occur, which is not dose-dependent.

The side effects due to the corticosteroid component hydrocortisone include increased intraocular pressure (development of glaucoma), combined, in very rare cases, with damage of the optic nerve; formation of posterior subcapsular cataract (a type of clouding of the eye's lens); delayed healing of ocular wounds. Cases of perforation (a breakdown of the eye) have been reported, when corticosteroids were used in diseases causing thinning of the cornea and sclera. With prolonged use, clouding of the lens and development of superficial keratitis (inflammation of the cornea) are possible.

Secondary infection: the development of secondary infection resulting from the use of combined medicinal products, containing a corticosteroid and an antimicrobial component, is possible.

The eyes treated continuously with topical corticosteroids are more prone to the occurrence of corneal fungal infections.

The secondary infection might be the result of a suppressed defensive response of the body.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

5. How to store Hydrocortison cum Chloramphenicol

Store below 25⁰C.

Store in the original package.

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

Do not freeze.

Discard the tube 4 weeks after first opening to prevent any infection and contamination.

Do not use Hydrocortison cum Chloramphenicol after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice a change in the colour and consistency of the eye ointment.

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 Hydrocortison cum Chloramphenicol contains

- The active substances in 1 gram of the eye ointment are hydrocortisone acetate of 5.0 mg, chloramphenicol of 2.0 mg.
- The other ingredients are methyl parahydroxybenzoate; propyl parahydroxybenzoate; wool fat (lanolin); paraffin, hard; paraffin, liquid; paraffin, white soft (Vaseline album).

What Hydrocortison cum Chloramphenicol looks like and contents of the pack

Eye ointment

White to pale-yellow ointment with homogenous consistency, lanolin odour and no agglomerates and air bubbles.

Sterile, aluminium, cannula-fitted, lacquered tubes with a latex ring at the lower end, closed with a plastic screw cap fitted with a tamper-evident ring, with markings as per the approved colour mock-ups.

One tube (3 g) with a patient leaflet is inserted in a carton, with markings as per the approved colour mock-ups.

Marketing Authorisation Holder

Antibiotic-Razgrad AD

Office 201, 68 „Aprilsko vastanie” Blvd.

Razgrad 7200, Bulgaria

Tel.: +359 (84) 613 301

Fax: +359 (84) 634 272

E-mail: office@antibiotic.bg

Manufacturer

Balkanpharma-Razgrad AD

68 “Aprilsko vastanie” Blvd.

Razgrad 7200, Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Antibiotic-Razgrad AD

Office 201, 68 „Aprilsko vastanie” Blvd.

Razgrad 7200, Bulgaria

This leaflet was last revised in April 2011.