

HIDROKORTIZON SA HLORAMFENIKOLOM

(10 mg + 2 mg) / ml, eye drops, suspension

HYDROCORTISONE, CHLORAMPHENICOL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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?

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1. WHAT HIDROKORTIZON SA HLORAMFENIKOLOM IS AND WHAT IT IS USED FOR

HIDROKORTIZON SA HLORAMFENIKOLOM eye drops is a combination medicine containing anti-infective ingredient – chloramphenicol which is a broad spectrum antibiotic and anti-inflammatory ingredient - hydrocortisone which is a synthetic corticosteroid.

Chloramphenicol destroys organisms that cause infections in by inhibiting protein synthesis in their cells and thereby it has favorable effect on ocular infection. Chloramphenicol provides anti-inflammatory, anti-allergic and anti-exudative effect. It suppresses the inflammatory response of the body to the mechanical, chemical and immunological agents.

HIDROKORTIZON SA HLORAMFENIKOLOM eye drops are indicated for the topical inflammatory and allergic conditions of the eye lid, cornea and the front of the eye, when the use of corticosteroids is recommended, as well as for bacterial infection caused by microorganisms sensitive to chloramphenicol, which already exist or infections that can develop.

How hidrokortizon sa hloramfenikolom eye drops work?

These eye drops are a combination of pharmaceutical composition comprising the broad spectrum antibiotic chloramphenicol and synthetic corticosteroid hydrocortisone.

Chloramphenicol is bacteriostatic which has an aromatic structure. It inhibits peptidyl transferase and interferes with the protein synthesis in the bacterial cell.

Antibacterial spectrum of chloramphenicol includes a wide range of pathogenic microorganisms: Gram-positive - Staphylococcus aureus; Streptococcus pneumoniae, Streptococcus pyogenes, other β -haemolytic streptococci, aerobic gram-negative organisms - Escherichia coli, Haemophilus influenzae, Klebsiella / Enterobacter species; Moraxella lacunata in Neisseria species.

Chloramphenicol does not provide adequate protection against Pseudomonas aeruginosa and Serratia marcescens. It has a low activity against bacteria resistant to acid.

Hydrocortisone has anti-inflammatory, anti-allergic anti-exudative, immunosuppressant effect. It suppresses the response of the inflammatory body against mechanical, chemical and immunological agents. Its mechanism of action is achieved by inhibiting the activity of hyaluronidase, reducing capillary permeability and increasing polymerization of hyaluronic acid.

When are hidrokortizon sa hloramfenikolom eye drops used?

These eye drops are indicated for the topical inflammatory and allergic conditions of the eye lid, cornea and the front of the eye, when the use of corticosteroids is recommended, as well as for bacterial infection caused by microorganisms sensitive to chloramphenicol, which already exist or infections that can develop.

2. BEFORE YOU TAKE HIDROKORTIZON SA HLORAMFENIKOLOM

Do not take HIDROKORTIZON SA HLORAMFENIKOLOM

- If you are allergic to active substances or any of the other ingredients of this medicine;
- If you have a corneal ulcer
- If you have herpes simplex cornea, viral diseases of the cornea
- If you have an eye infection caused by mycobacteria
- If you have trachoma (a chronic inflammatory disease of the cornea caused by chlamydia)
- If you have a yeast infection of the eye
- If you have low levels of bone marrow (myelopathy, aplastic anemia)

This medicine should not be given to children under 3 years of age.

Take special care with HIDROKORTIZON SA HLORAMFENIKOLOM

Prolonged use of corticosteroids may increase the intra-ocular pressure (glaucoma), causing damage to the optic nerve, damage to the visual field and a reduction of visual acuity, leading to the creation of back subcapsular cataract (clouding that develops in the eye). Therefore, it is necessary to regularly monitor the intra-ocular pressure.

Prolonged use can suppress the body's defense responses, and thus increase the risk of secondary ocular infections.

In these diseases, which lead to a thinning of the cornea or sclera, topical use of steroids can result in perforation.

In the state of purulent eye steroids can mask or enable existing infection.

Prolonged use may lead to the development of resistant microorganisms, including fungi. In case of superinfection, the appropriate therapy shall be applied.

It is recommended to avoid wearing contact lenses during treatment.

Taking other medicines

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

Chloramphenicol solutions are not compatible with erythromycin, tetracycline and polymyxin B.

The concomitant use of anticholinergic agents (atropine) may lead to increase of intraocular pressure.

Simultaneous use with products that suppress the formation of blood cells may enhance the pressing effect of chloramphenicol on the bone marrow.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking medicine.

There are no data on the damage to the fetus during pregnancy; However, the use of this medicine is recommended only when it is absolutely necessary and after careful assessment of the relationship between benefits and risk.

The use of this medicine is not recommended during breast-feeding, since the metabolism of an infant is underdeveloped, there are potential risks of accumulation of chloramphenicol, which can result in depression of bone marrow function.

Driving and using machines

Some patients can experience problems such as blurred vision while using HIDROKORTIZON SA HLORAMFENIKOLOM. Patients with blurred vision should not be driving or using machines.

HIDROKORTIZON SA HLORAMFENIKOLOM contains benzalkonium chloride

Benzalkonium chloride may cause eye irritation and discoloration of soft contact lenses.

3. HOW TO TAKE HIDROKORTIZON SA HLORAMFENIKOLOM

Due to the presence of boric acid, this medication should not be used children under 3 years.

Always use HIDROKORTIZON SA HLORAMFENIKOLOM exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Topical ocular use

The dosage and duration of treatment is determined by the doctor.

The usual dose is 1-2 drops in the affected eye (s) four to six times a day, depending on the severity of the disease. In the condition is serious, the dose may be increased to 2 drops in the affected eye (s) every two hours during the first 48-72 hours, until improvement is achieved, and the dose should be gradually decreased after clinical symptoms improve. Do not drip more than two drops in one application.

It is recommended to use the eye drops during the day and ointment at night.

Treatment should be continued until symptoms of the disease disappear (5-7 days on average), but not more than 14 days.

Children

Safety and efficacy in children under three years of age has not been established.

Instructions for use

Eye drops should be used in the following way:

- Shake the bottle before use.
- Tilt your head back.
- Using your index finger, pull the lower eyelid away from your eye to form a pouch.
- Place the eye drops into the pouch
- Do not touch the dropper tip of the bottle to any surface, including the eye.
- Look down and then close the eye.

If you use more HIDROKORTIZON SA HLORAMFENIKOLOM than you should

If you take too much, or if you accidentally swallow the eye drops, immediately talk to your doctor or pharmacist, or go to the nearest hospital.

If you have followed instructions for use, overdose and toxicity will not occur in a topical application of this medicine.

Clinically manifested symptoms of overdose with these eye drops are similar to side effects: redness, watery eyes, eyelid edema and itching.

If you experience symptoms of overdose, immediately contact your doctor.

If you forget to take HIDROKORTIZON SA HLORAMFENIKOLOM

If you forgot to apply HIDROKORTIZON SA HLORAMFENIKOLOM eye drops do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, HIDROKORTIZON SA HLORAMFENIKOLOM can cause side effects, although not everybody gets them.

Side effects that can occur during the administration of HIDROKORTIZON SA HLORAMFENIKOLOM eye drops may be related to antibacterial ingredient, steroid ingredient or a combination of these ingredients.

The most common side effects associated with the topical ocular administration of chloramphenicol are: allergic reactions and local irritation manifested as itching, swelling and redness of the eyelid. However, very rarely it can cause bone marrow depression and aplastic anemia, which are not dependent on the dose (sudden reduction in the number of all types of blood cells due to suppressed production of bone marrow).

Side effects that may be associated with a steroid ingredient (hydrocortisone) include: possible increase in intra-ocular pressure, glaucoma, very rarely associated with damage to the optic nerve, formation of back subcapsular cataracts (clouding that develops in the eye), and delayed treatment of ocular injuries. The perforations were observed with the use of corticosteroids for the treatment of diseases that lead to thinning of the cornea and sclera.

Prolonged use may be associated with discoloration of the lens and the development of surface keratitis.

Secondary infections: secondary infections most often develop as a result of the use of combination of medicines containing steroids and anti-microbial ingredients. Eyes treated with topical corticosteroids in the short-term period are predisposed to additional fungal infection of the cornea. Secondary infections can be the result of suppressed physical defense responses.

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

5. HOW TO STORE HIDROKORTIZON SA HLORAMFENIKOLOM

Keep out of the reach and sight of children.

Throw the opened bottle 28 days after opening.

Store below 25 °C. Do not freeze the medicine.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

The shelf life of medicine is indicated on the packaging of the medicine.

6. FURTHER INFORMATION

What HIDROKORTIZON SA HLORAMFENIKOLOM contains

Active substances in 1 ml of the suspension: 10 mg of hydrocortisone and 2 mg of chloramphenicol.
Other ingredients are: benzalkonium chloride, boric acid, potassium chloride, anhydrous sodium carbonate solution, polysorbate 80, hydroxyethyl cellulose, liquids for injection

What HIDROKORTIZON SA HLORAMFENIKOLOM looks like and contents of the pack

HIDROKORTIZON SA HLORAMFENIKOLOM eye drops suspension is white to pale yellow.

Eye drops, suspension in bottles of 5 mL, with a dropper and threaded polypropylene cap which prevents unauthorized opening.

One bottle in a cardboard box with instructions for use.

Pharmacotherapeutic group: ophthalmic preparations, corticosteroids and antibiotics.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Actavis Group PTC ehf
Rekjavikurvegur 76-78, P.O. Box Hafnarfjordur, Iceland

Manufacturer of the medicinal product

Balkanpharma-Razgrad AD
Aprilska 68 vastanie Blvd, Sofia, Bulgaria