

Package leaflet: Information for the patient

Dexamphenicol 5 mg/1 ml + 1 mg/1 ml eye drops, solution Chloramphenicol/Dexamethasone

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.

What is in this leaflet

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3. How to use Dexamphenicol
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1. What Dexamphenicol is and what it is used for

The name of your medicine is Dexamphenicol. It contains as active substances the antibiotic chloramphenicol and the corticosteroid dexamethasone. Chloramphenicol inhibits the development and multiplication of bacteria causing common infections in humans. Dexamethasone has a strong anti-inflammatory effect.

Dexamphenicol is indicated for the treatment of inflammations of the eye, where the use of corticosteroids is appropriate and in cases, where there is an existing infection or a risk of infection, caused by bacteria, susceptible to the action of chloramphenicol.

2. What you need to know before you use Dexamphenicol

Do not use Dexamphenicol:

- if you are allergic to chloramphenicol, dexamethasone or any of the other ingredients of this medicine (listed in section 6);
- if you have an injury or ulcer of the cornea;
- if you suffer from eye infections caused by viruses (for example, Herpes virus) or fungi;
- if you have severe blood disorders or someone in your family suffers from impaired bone marrow function;
- if you have known impaired liver function.

This medicine should not be administered to newborns aged up to 28 days.

Warnings and precautions

Talk to your doctor or pharmacist before using Dexamphenicol.

- You need to know that long-term treatment with chloramphenicol, including when applied in the eye, may lead to suppression of the bone marrow function. The bone marrow is responsible for the formation of blood cells.

- As with other antibiotics, prolonged use of chloramphenicol may lead to the development of non-susceptible microorganisms or fungi. In this case, your doctor will prescribe other, appropriate therapy. Dexamethasone, in turn, may mask the signs of such an infection or its exacerbation.
- Prolonged use of corticosteroids, including dexamethasone, may lead to some unfavourable effects:
 - An increase of the pressure in the eye may occur. If you have such a predisposition or you suffer from glaucoma, your doctor will monitor the intraocular pressure, especially if you require a long-term treatment.
 - Long-term treatment, especially at higher doses, may lead to the formation or worsening of cataract.
 - With prolonged use of corticosteroids in the eye, disturbance of corneal integrity may occur, if you suffer from diseases that lead to its thinning. Caution is required, if simultaneously with this medicine, you apply in the eye medicines of the group of non-steroidal anti-inflammatory drugs.
 - In case you have recently had a cataract surgery, the application of corticosteroids in the eye may delay healing and increase the incidence of formation of bullae.
 - In case you have diabetes, you need to tell your doctor before you start treatment with this medicine. You may have a predisposition to increased eye pressure and/or formation of cataract. In this case, your doctor will assess the benefits and risks for you from this treatment.
- This medicine should not be used for more than 10 days. You must talk to your doctor if you do not feel better after 3 days from the initiation of treatment.
- If you have an eye infection caused by bacteria, wearing contact lenses is contraindicated until complete resolution of the symptoms of the disease and discontinuation of the treatment with the product.
- This medicine should be used with caution in infants aged 28 days to three months and children under 2 years of age.

Other medicines and Dexamphenicol

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

Dexamphenicol should not be administered simultaneously with certain types of antibiotics (penicillin, cephalosporin, gentamicin, tetracycline, vancomycin, etc.), since these may decrease or inhibit the activity of chloramphenicol.

This medicine should not be used if you are treated with medicines for diabetes (sulphonylurea agents), those for decreasing blood coagulation (coumarin derivatives), hydantoins, methotrexate, since impaired blood formation may occur.

Co-administration of this medicine and non-steroidal anti-inflammatory drugs (diclofenac, indomethacin, etc.), intended for use in the eye, is undesirable if you have previously had inflammation of the cornea.

Pregnancy, breast-feeding and fertility

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 using this medicine.

If you are pregnant, attempting to become pregnant or breast-feeding, you should not use Dexamphenicol.

Driving and using machines

As with all eye drops, temporary blurred vision or other disturbances that may affect the ability to drive or use machines may occur after instillation.

After instilling Dexamphenicol in the eye, wait until your vision clears before you start using machines or driving.

Dexamphenicol contains benzalkonium chloride

Benzalkonium chloride may cause eye irritation.

Avoid contact with soft contact lenses. Remove your contact lenses before applying the eye drops and wait at least 15 minutes before reinsertion.

Benzalkonium chloride is known to discolour soft contact lenses.

3. How to use Dexamphenicol

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

The recommended dose is:

Adults and persons over 65 years

1 drop of the solution is instilled 3-5 times daily in the affected eye/eyes. In severe infections, your doctor may order the application of 1 drop every hour.

Dexamphenicol is instilled in both eyes only after you have been told so by your doctor, who has found that the disease has affected both eyes.

The duration of treatment should not be longer than 10 days.

Upon co-administration of other product for use in the eye, the interval between the two should be at least 5 minutes.

Keeping hygiene during the instillation of the drops is of importance. Avoid the contact between the tip of the bottle and the eye, eyelid or adjacent surfaces, since the tip may be contaminated, thus leading to the development of eye infection with serious sequels for the eye, even to loss of vision. Always wash your hands before using the bottle!

If you think that your bottle is contaminated, contact your doctor before continuing the application of these eye drops.

Children

This medicine should not be administered to newborns aged up to 28 days.

In case of treating children with Dexamphenicol, it is essential to press on the inner corner of the eye for 3 minutes after instillation, in order to reduce the possibility of the medicine to pass into the nose (read carefully the information in the Instructions for use).

Instructions for use

1. Before you start using the bottle, make sure that the protective strip between the cap and the bottle is not broken. Wash your hands and unscrew the cap.



2. Tilt your head slightly backwards and pull the lower eyelid downwards. Thus, a pouch is formed between the eyelid and the eye. The eye drop will fall just into this place.
3. Hold the bottle downwards. Put its tip close to the eye. Use a mirror, if helpful.
4. Pay attention not to touch the tip of the bottle to the eye, eyelid or adjacent surfaces. Press carefully the bottle base to let fall a drop of the solution. Only a slight pressure on the bottle bottom is needed.

5. After you have instilled the medicine, close the eyelid and by using your finger, press on the corner of your eye near your nose for 3 minutes. This will prevent Dexamphenicol from passing into the nose or running out.

6. If it is necessary to apply the eye drops in both eyes, repeat all previously described steps for the other eye.
7. Close tightly the bottle immediately after use.

If the eye drop fails to fall in the eye, try again.

Use this bottle of Dexamphenicol for your eyes only!

If you use more Dexamphenicol than you should

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

If you have instilled a greater dose than the prescribed, rinse thoroughly the eye/eyes with lukewarm water. In case you have accidentally swallowed the contents of the bottle, ask your doctor for advice.

If you forget to use Dexamphenicol

Do not apply a double dose to make up for a forgotten dose. Apply your dose as soon as you remember. If it is almost the time for your next dose, follow your regular dosing schedule.

If you stop using Dexamphenicol

You doctor will decide when you should discontinue the treatment. Do not stop using the medicine unless your doctor has ordered so. In these cases, the symptoms of the disease may reappear and in addition, you may also help for the development of bacteria resistant to the action of chloramphenicol.

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

4. Possible side effects

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

Dexamphenicol contains two active substances and therefore, the side effects may be related to each of them.

The possible side effects of the treatment with this medicine include:

Blood and lymphatic system disorders

Rarely, there may be abnormalities in blood formation, sometimes irreversible and fatal, which present with reductions in some or all types of blood cells, for example, anaemia (reduction of the red blood

cells), leukopenia (reduction of the white blood cells), thrombocytopenia (reduction of the cells that help blood clotting), agranulocytosis (severe reduction to complete lack of the white blood cells).

Immune system disorders

There have been reports of severe allergic reactions that cause difficulty in breathing or dizziness, and skin inflammations (eczema), involving the lip corners.

Nervous system disorders

Rarely, chloramphenicol may cause reversible inflammation and damage of the optic nerve.

Eye disorders

Most commonly, itching, redness or swelling of the eyelid, foreign body sensation or appearance of other sign of irritation, missing before the initiation of treatment have been reported.

There have been reports of burning and stinging in the eye and blurred vision.

The possible side effects related with corticosteroid use in the eye are increased intraocular pressure and subsequent development of glaucoma, cataract, eye infections, delayed wound healing and corneal thinning and laceration, "sinking" of the eye, dilation of the pupil.

Gastro-intestinal disorders

After applying this medicine, you may have a bitter taste in the mouth, due to the presence of chloramphenicol in it.

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:

Bulgarian Drug Agency

8 "Damyan Gruev" Str.

1303 Sofia

Tel.: +359 2 8903417

website: www.bda.bg.

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

5. How to store Dexamphenicol

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

Store in the original package.

Before opening the package, store in a refrigerator (2°C - 8°C).

After opening the package, store at a temperature below 25°C.

Do not use this medicine after the expiry date which is stated on the carton after „EXP”. The expiry date refers to the last day of that month.

After first opening the package, you may use this medicine for 28 days.

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 Dexamphenicol contains

- The active substances of this medicine are chloramphenicol and dexamethasone. 1 ml solution contains 5 mg of chloramphenicol and 1 mg of dexamethasone.
- The other ingredients (excipients) are benzalkonium chloride; disodium phosphate dihydrate; sodium dihydrogen phosphate, dihydrate; disodium edetate; macrogol 400, macrogolglycerol ricinoleate, water for injections.

What Dexamphenicol looks like and contents of the pack

Eye drops, solution (colourless to pale yellow opalescent liquid).

White plastic bottle fitted with a dropper applicator and closed with a screw cap with a tamper-evident ring. 1 (one) bottle of 5 ml with a patient leaflet is inserted in a cardboard carton.

Marketing Authorisation Holder

Antibiotic-Razgrad AD
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7200 Razgrad, Bulgaria

Manufacturer

Balkanpharma-Razgrad AD
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7200 Razgrad, Bulgaria

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

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