

PACKAGE LEAFLET: INFORMATION FOR THE USER

ToboDexin 3 mg/g+1 mg/g eye ointment

Tobramycin + Dexamethasone

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What ToboDexin is and what it is used for
2. Before you use ToboDexin
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1. WHAT TOBODEXIN IS AND WHAT IT IS USED FOR

ToboDexin is a combined product, containing dexamethasone and tobramycin, and is intended for ocular use.

Dexamethasone is a corticosteroid with a pronounced anti-inflammatory effect.

Tobramycin is an aminoglycoside antibiotic, which is active against a large number of microorganisms causing frequently infections of the eyes.

ToboDexin eye ointment is indicated for the treatment of eye inflammation with suspected or presented infection, caused by tobramycin-susceptible bacteria.

This inflammation may be due to an injury, performed surgical intervention, available foreign body or infection.

2. BEFORE YOU USE TOBODEXIN

Do not use ToboDexin

- if you are allergic (hypersensitive) to tobramycin and/or dexamethasone or any of the other ingredients of ToboDexin;
- if the eye infection is caused by viruses or fungi. You should know that only the physician may decide whether the infection is suitable for treating with this product.

Take special care with the use of ToboDexin

If you have elevated intraocular pressure (glaucoma), your doctor will decide whether this product is suitable for treating your disease, since dexamethasone may lead to an increase of the intraocular pressure. In some cases, its periodical monitoring may be required during the treatment.

In certain diseases, topical corticosteroids may result in damage of some parts of the eye (the sclera or cornea), and during prolonged use, they may delay ocular wound healing or increase the predisposition to eye infections.

The application of antibiotics of this group in the eye may provoke an allergic reaction in some patients, which most commonly presents with itching, reddening and swelling of the eyelids, excessive tear discharge. In such a case, the use of the medicinal product should be discontinued. You should know that if you have or have had allergy to other antibiotics of this group (for example, gentamicin) an allergic reaction is more likely to occur.

Prolonged use of the product may result in development of resistant microorganisms and, respectively, to a decreased treatment effect. Sometimes, an additional infection of other microorganisms may develop, including fungi. In these cases, the physician will administer the appropriate therapy.

You should not wear contact lenses in case of available eye infection and during the course of treatment with the product.

Taking other medicines

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

In case of simultaneous application with other aminoglycoside antibiotics, you should inform about this your doctor, who will decide whether there is a need to monitor their total level in the blood.

Simultaneous use with the so-called anticholinergic agents may result in an increase of the intraocular pressure.

Pregnancy and breast-feeding

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

The treatment with aminoglycoside antibiotics may result in damage of the auditory nerve and deafness. Topical corticosteroid use in animals may lead to foetal damages, although such data are not known for humans. During ocular use, however, the penetration of tobramycin and dexamethasone into the blood is low; the risk of ToboDexin use is considered also as non-increased. However, the product use during pregnancy and for the period of breast-feeding is recommended only in case of clear necessity and after careful evaluation of the benefit/risk ratio.

Driving and using machines

Transient blurring or other disturbances of vision may occur, which may affect the ability to drive and use machines. If this happens, you should wait until your vision clears, and then start driving or operating machines.

3. HOW TO USE TOBODEXIN

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

Adults, adolescents and elderly

Recommended dose in mild and moderate infections – a small amount of the medicine (a strip with length of about 1.5 cm) is inserted into the affected eye/eyes, every four to six hours. In severe infections, the product may be applied more frequently. This will be decided by your doctor. You should know, that your doctor will determine the duration of your treatment. In eye surgery (for example of a cataract), the treatment may continue for up to several weeks.

If your condition does not improve, you should consult the physician. You should not discontinue the treatment before asking the physician for advice.

Use in children

The product can be used in children over one year of age, following the exact instructions of the physician. The product use is not recommended in younger children, since there are no data of its safe application.

Use in patients with hepatic and renal diseases

No change of the recommended dose is required in these patients, since no high concentrations of the active substances have been observed in the blood following ocular use.

Method of administration

ToboDexin eye ointment is applied in the following manner:

- before applying the medicine, you need to wash your hands;
- tilt your head slightly backwards;
- place your finger on the cheek, just below the eye and carefully pull the lower eyelid downwards to form a pouch between the eye and the eyelid;
- insert the amount of the medicine, prescribed by the physician, into this pouch;
- the tip of the tube should not touch the eye, eyelid or other adjacent tissues and surfaces, since this may contaminate the medicine.

- after you have applied the medicine, look downwards, blink several times to enable the spread of the ointment on the entire ocular surface and then close the eye for some seconds.

- after use, immediately close the tube tightly.

If you are also on treatment with other products intended for ocular use, apply them consecutively, at intervals of at least 5 - 10 minutes, as these in the form of an ointment should be applied last.

If you use more ToboDexin than you should

Do not apply the medicine more frequently or for a longer time than this, determined by the physician, in order to avoid overdose. If you, however, have accidentally used more than the dose prescribed, contact your doctor or pharmacist, although it is usually sufficient to bathe the eye abundantly with tempered boiled water.

When adhering strictly to the instructions for use of the product, overdose is unlikely to occur. In the event of oral intake through carelessness, the amount that will enter the blood is also negligible.

If you forget to use ToboDexin

Do not use an amount greater than the required one to make up for a forgotten application. Apply the usual dose as soon as you remember and continue the treatment in the usual manner.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ToboDexin can cause side effects, although not everybody gets them. If this happens, tell your doctor. The frequencies, indicated for the side effects, are defined as follows: common ($\geq 1/100$ to $< 1/10$) – affect more than one in 100 patients and less than one in 10 patients; very rare ($< 1/10,000$) – affect less than one in 10,000 patients.

Side effects may be related to dexamethasone, tobramycin or the combination itself. During treatment with the product, the following side effects are likely to occur:

Eye disorders

Common – itching and reddening of the eyes, excessive tear discharge;

Uncommon – ocular allergic reactions, secretion release, discomfort in the eyes, swelling and reddening of the eyelid, other problems with the eyelid, increase of the intraocular pressure, delayed ocular wound healing, development of infections.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TOBODEXIN

Keep out of the reach and sight of children.

Do not use ToboDexin after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. In-use period after first opening of the pack: 28 days.

Store below 25°C.

Do not use ToboDexin if you notice any changes in the appearance or other signs of deterioration of the ointment. Ask your pharmacist for advice.

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

6. FURTHER INFORMATION

What ToboDexin contains

The active substance in 1 gram of the eye ointment is tobramycin of 3.0 mg (as sulfate) and dexamethasone of 1.0 mg.

The other ingredients are methyl parahydroxybenzoate; propyl parahydroxybenzoate; paraffin, liquid; paraffin, white soft.

What ToboDexin looks like and contents of the pack

ToboDexin eye ointment is a white to pale-yellow ointment with homogenous consistency, no agglomerates and air bubbles.

ToboDexin eye ointment is packed in lacquered tubes with a tip, closed with a plastic screw cap.

One tube with a patient leaflet is inserted in a cardboard carton.

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