

Tobramycin/Dexamethasone 3mg/ml + 1mg/ml eye drops, suspension

tobramycin, 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 symptoms are the same as yours.
- If you have 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

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

1 What Tobramycin/Dexamethasone is and what it is used for

This medicine contains dexamethasone, a corticosteroid, and tobramycin, an antibiotic which is active against a wide range of bacteria that may infect the eye.

It is used to prevent and treat inflammation and prevent possible infection of the eye after cataract surgery in adults and children aged 2 years and older.

2 What you need to know before you use Tobramycin/Dexamethasone

Do not use Tobramycin/Dexamethasone:

- If you have or think that you have any type of infection of the eye. Use of corticosteroids may make infections worse.
- If you have sticky discharge from your eye.
- If you have a red eye that has not been seen by a doctor.
- If you are allergic to tobramycin, dexamethasone or any of the other ingredients of this medicine (listed in section 6).

If any of these apply ask your doctor for advice.

Warnings and precautions

If any of these apply to you, talk to your doctor or pharmacist before taking this medicine:

- If you have a disorder causing a thinning of the eye tissues, such as rheumatoid arthritis, Fuch's dystrophy or following a corneal transplant. Corticosteroids may cause further thinning and possible perforation, and may delay the healing of your eye wound.
- Topical non-steroidal anti-inflammatory drugs (NSAIDs) are also known to slow or delay wound healing. If you use topical NSAIDs and corticosteroids together, it may increase the potential for healing problems.
- If you experience allergic reactions with this medicine, discontinue use and consult your doctor. Allergic reactions may vary from localised itching or skin redness to severe allergic reactions (anaphylactic reaction) or serious skin reactions. These allergic reactions may occur with other topical or systemic antibiotics of the same group (aminoglycosides).
- If your symptoms get worse or suddenly return, please consult your doctor. You may become more susceptible to eye infections with the use of this medicine.
- If you are diabetic please consult your doctor. There is an increased risk of corticosteroid-induced increased intraocular pressure and/or cataract formation in diabetic patients.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- If you are using other antibiotic treatment, including oral, with Tobramycin/Dexamethasone, ask your doctor for advice.
- If you have or if you have ever had conditions such as myasthenia gravis (neuromuscular disorder that causes weakness in the skeletal muscles) or Parkinson's disease (a progressive nervous system disorder that affects movement), ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness.
- If you use Tobramycin/Dexamethasone for a long period of time, you may become more susceptible to eye infections, have increased pressure in your eye(s) or develop cataracts.
- Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome. Suppression of the adrenal gland function may develop after stopping long-term or intensive treatment with Tobramycin/Dexamethasone. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a medicine containing ritonavir or cobicistat.
- Signs and symptoms of adrenal suppression include fatigue; light-headedness upon standing or difficulty standing, muscle weakness, fever, weight loss, anxiety, nausea, vomiting, diarrhoea, headache, sweating, changes in mood or personality, and joint and muscle pains.

You may still be able to use this medicine, but discuss it with your doctor first.

- Intraocular pressure should be checked frequently, this is especially important in children below 6 years of age receiving dexamethasone-containing products.
- Do not give this medicine to children under 2 years old because the safety and efficacy in this population has not been established.

Other medicines and Tobramycin/Dexamethasone

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

Especially tell your doctor if you are using topical NSAIDs. If you use topical steroids and topical NSAIDs together, it may increase eye healing problems.

Tell your doctor if you are using ritonavir or cobicistat (medicines used in the treatment of HIV), as this may increase the amount of dexamethasone in the blood.

If you are using other eye drops or eye ointments, wait at least 5 minutes between using each one. Eye ointments should be administered last.

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 taking this medicine.

Tobramycin/Dexamethasone is not recommended during pregnancy or while breast-feeding.

Driving and using machines

If you experience temporary blurred vision after using Tobramycin/Dexamethasone you should not drive or operate machinery until your vision is clear.

Important information if you wear Contact Lenses

Contact lens wear is not recommended during treatment of an ocular infection or inflammation.

Tobramycin/Dexamethasone contains benzalkonium chloride

This medicine contains 0.1mg benzalkonium chloride in each ml of suspension.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3 How to use Tobramycin/Dexamethasone

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

Only use Tobramycin/Dexamethasone for dropping in your eye(s).

The recommended dose is 1 drop in the affected eye(s) every 4 to 6 hours while you are awake. During the initial 48 hours, your doctor may increase the dose to 1 drop every 2 hours.

Use this medicine for as long as your doctor told you to. Do not use for more than 24 days.

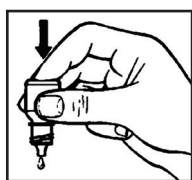
Tobramycin/Dexamethasone may be used in children 2 years of age and older at the same dose as in adults.

Before using this medicine for the first time, make sure the tamper evident ring is unbroken.

Instructions for use



1



2



3

1. Wash your hands before you start.
2. Shake the bottle well.
3. Twist off the bottle cap. Remove the loose collar from the cap when the bottle is first opened.
4. Hold the bottle pointing down, between your thumb and fingers.
5. Tilt your head back.
6. Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (**picture 1**).
7. Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
8. Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could contaminate the drops.
9. Gently press on the base of the bottle to release one drop at a time (**picture 2**).
10. Do not squeeze the bottle, only a gentle press on the bottom is needed.
11. After using Tobramycin/Dexamethasone, keep the eyelid closed, while simultaneously applying gentle pressure with a finger to the corner of your eye, by the nose for at least 1 minute (**picture 3**). This helps to limit the amount of medicine that will get into the rest of the body.

12. If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.

13. If a drop misses your eye, try again.

The dispenser tip is designed to provide a single drop; do NOT enlarge the hole of the dispenser tip.

If you use more Tobramycin/Dexamethasone than you should

It can be washed out with warm water. Don't put in any more drops until it's time for your next regular dose. If you recently had eye surgery, reach out to your doctor or pharmacist for detailed instructions.

If you forget to use Tobramycin/Dexamethasone

If you forget to take a dose, apply it as soon as possible. Do not take a double dose to make up for a forgotten dose.

If you wear soft contact lenses

Do not use the drops with your lenses in. After using the drops wait 15 minutes before putting your lenses back in.

If you are using other eye preparations such as eye drops or eye ointment

Leave at least 5 minutes between putting in Tobramycin/Dexamethasone and the other eye preparations. Eye ointments should be administered last.

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

4 Possible side effects

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

If you notice any of the following possible side effects, stop using this medicine and seek urgent medical advice immediately:

- itchy rash or hives;
- swelling of the face, lips, tongue or other parts of the body;
- shortness of breath/wheezing;
- severe skin reactions such as blistering which may be accompanied by sore throat, fever or headache.

The following side effects may be seen with Tobramycin/Dexamethasone:

Uncommon: may affect up to 1 in 100 people

Affecting the eye: increased pressure in your eye(s), eye irritation, eye pain, eye itching, watery eyes, eye discomfort.

Affecting the body: headache, runny nose, tightness of the throat.

Rare: may affect up to 1 in 1000 people

Affecting the eye: redness, blurred vision, dry eye(s), eye allergy, eye surface inflammation.

Affecting the body: bad taste.

Not known: frequency cannot be estimated from the available data

Affecting the eye: increase in pupil size, eyelid redness, eyelid swelling, increased tear production.

Affecting the body: dizziness, nausea, abdominal discomfort, rash, swelling of the face, itching.

Hormone problems: growth of extra body hair (mainly in women), muscle weakness and muscle breakdown, purple stretch marks on the skin, increased blood pressure, irregular or missing periods, changes in the amounts of proteins and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").

If Tobramycin/Dexamethasone is used for more than 24 days, it may cause you to get an infection and the healing of your wound may be also delayed.

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 the Yellow Card Scheme, Website: <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Tobramycin/Dexamethasone

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

This medicine does not require any special storage conditions.

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

Throw the bottle away 4 weeks after opening, to prevent infections.

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 Tobramycin/Dexamethasone contains

- The active substances are tobramycin and dexamethasone. Each ml of suspension contains 3mg of tobramycin and 1mg dexamethasone.
- The other ingredients are hydroxyethylcellulose, benzalkonium chloride, edetate disodium, tyloxapol, sodium chloride, sodium sulfate anhydrous, sulfuric acid for pH-adjustment and water for injections.

What Tobramycin/Dexamethasone looks like and contents of the pack

Tobramycin/Dexamethasone is a white homogeneous suspension. This medicine is supplied in a 10ml LDPE dropper white bottle with a screw cap and a tamper evident ring.

Each bottle contains 5ml of suspension.

This medicine is available in packs of 1 bottle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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P H A R M A

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