

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tobradex[®] Eye Drops, Suspension (tobramycin / dexamethasone)

The name of your medicine is Tobradex[®] Eye drops but will be referred to as Tobradex throughout the remainder of this leaflet

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

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

1. What Tobradex is and what it is used for

Tobradex 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 Tobradex

Do not use Tobradex...

- 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 a **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 or dexamethasone or to any of the other ingredients listed in (section 6).
- If any of these apply ask your doctor for advice.

Warnings and precautions

If any of these applies to you, talk to your doctor or pharmacist before taking Tobradex.

- 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 healing. If you use topical NSAIDs and corticosteroids together, it may increase the potential for healing problems.
- If you experience allergic reactions with Tobradex, discontinue use and consult your doctor. Allergic reactions may vary from localized 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 family (aminoglycoside type).
- 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 product.
- If you are diabetic please consult your doctor. The risk of corticosteroid-induced increase intraocular pressure and / or cataract formation is increased 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 Tobradex, 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 Tobradex 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 a long-term or intensive treatment with Tobradex. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called 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 Tobradex, 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 Tobradex to children below 2 years old because the safety and efficacy in this population has not been established.

Other medicines and Tobradex

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

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 and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Tobradex is not recommended during pregnancy or breastfeeding.

Driving and using machines

If you experience temporary blurred vision after using Tobradex 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. Tobradex contains benzalkonium chloride.

This medicine contains 0.5mg benzalkonium chloride in each 5 ml, which is equivalent to 0.1 mg/ml.

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 Tobradex

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Only use Tobradex for dropping in your eye(s).

The recommended dose

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. Do not use for more than **24 days**.