

Package Leaflet: Information for the patient

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

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. See section 4.

What is in this leaflet:

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

1. What [national name] is and what it is used for

[national name] contains dexamethasone, which has an anti-inflammatory effect. [national name] also contains tobramycin, which is an antibiotic effective against several bacteria that may cause eye infections.

[national name] is used to prevent and treat eye inflammations and prevent bacterial infections after cataract surgery in adults and children aged 2 years and older.

2. What you need to know before you use [national name]

Do not use [national name]:

- If you are allergic (hypersensitive) to tobramycin, dexamethasone or any of the other ingredients of the eye drops (listed in section 6).
- If you have or think you might have an infection of the eye
- If you have a sticky discharge from your eye
- If you have a red eye that has not been seen by a doctor

Warnings and precautions

Talk to your doctor or pharmacist before using [national name].

- If you have a disease that might cause thinning of eye tissue, such as rheumatoid arthritis, Fuch's dystrophy or after transplantation of the cornea, you should inform your doctor. Corticosteroids may cause further thinning and possible perforation
- If you experience allergic reactions such as eyelid itching, swelling or, redness of the eye with [national name], discontinue use and consult your doctor. This allergic sensitivity may occur with other topical or systemic antibiotic of 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.
- 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 [national name]. 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.
- Talk to your doctor if you have a neuromuscular disorder such as myasthenia gravis or Parkinson's disease. This medicine may aggravate muscle weakness.
- If you are using other antibiotic treatment, including oral, with [national name], ask your doctor for advice.
- If you are using nonsteroidal anti-inflammatory (NSAIDs) eye preparations with [national name], ask your doctor for advice. Concomitant use of eye preparations that contain nonsteroidal anti-inflammatory (NSAIDs) and eye preparations that contain steroids may increase the potential for healing problems.
- If you use [national name] for a long period of time you may become more susceptible to eye infections, have increased pressure in your eye(s) or develop cataracts.
- Intraocular pressure should be checked frequently, this is especially important in children below 6 years of age receiving dexamethasone-containing products.
- If you wear soft contact lenses, remove them before using this medicine and wait at least 15 minutes before reinsertion. This product contains benzalkonium chloride as preservative which may cause eye irritation and discolour soft contact lenses.
Contact lens wear is not recommended during treatment of an ocular infection or inflammation.

Children

Do not give [national name] to children below 2 years old because the safety and efficacy in this population has not been established.

Other medicines and [national name]

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

Concomitant use of eye preparations that contain nonsteroidal anti-inflammatory (NSAIDs) and eye preparations that contain steroids may increase the potential for healing problems.

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.

Tell your doctor if you are using ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.

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. Your doctor will tell you whether you can use [national name] or not.

Driving and using machines

If you experience temporary blurred vision after using [national name] you should wait until these symptoms are cleared before driving and using machines.

[national name] contains benzalkonium chloride

This medicine contains 0.1mg benzalkonium chloride in each ml which is equivalent to 0.5mg/5ml bottle. 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 [national name]

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

The recommended dose is:

One drop in the eye(s) every 4 to 6 hours, while you are awake. During the first 48 hours, your doctor may increase the dose to one drop every two hours, while you are awake.

Do not use more than 24 days.

Use in children and adolescents

[national name] may be used in children 2 years of age and older at the same dose as in adults.

Always wash your hands before applying eye drops.

Apply your eye drops in the following way:

1. Shake the bottle well.
2. Remove protective cap.
3. Tilt your head back and look at the ceiling.
4. Gently pull the lower eyelid down until there is a small pocket.
5. Squeeze the upturned dropper bottle to release a drop into your eye.
6. Whilst keeping the affected eye closed, press your finger against the corner of the closed eye (the side where the eye meets the nose) and hold for 1 minute.

Avoid touching the dropper tip against your eye or anything else.

Replace and tighten the cap straight after use.

If you take more [national name] than you should

A topical overdose of [national name] may be flushed from the eye(s) with lukewarm tap water.

If you forget to use [national name]

If you forget to take a dose, apply it as soon as you remember. If, however, it is almost time for your next dose, you should omit the missed dose altogether and then follow your normal routine.

If you stop using [national name]

Your doctor will tell you when to stop using [national name].

Inform your doctor if you need to interrupt the treatment.

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

4. Possible side effects

Like all medicines, [national name] can cause side effects, although not everybody gets them.

The following side effects have been seen

Uncommon side effects

(may affect up to 1 in 100 people)

Effects in the eye: increased pressure in your eye(s), eyelid redness, eyelid swelling, eye irritation, eye pain, eye itching, watery eyes, eye discomfort.

General side effects: headache, runny nose, tightness of the throat.

Rare side effects

(may affect up to 1 in 1000 people)

Effects in the eye: redness, blurred vision, dry eye, eye allergy, eye surface inflammation.

General side effects: bad taste

Not known

(frequency cannot be estimated from available data)

Effects in the eye: increase in pupil size, eyelid redness, increased tear production, eye surface inflammation.

Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein 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").

General side effects: allergy (hypersensitivity), dizziness, nausea, abdominal discomfort, rash, swelling of the face, itching.

If [national name] is used for more than 24 days, it may cause you to get an infection and the healing of your wound may also be 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 national reporting system [*to be completed nationally*]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [national name]

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

Do not use the bottle if the tamper-proof seal on the bottle is broken before first use.

Do not use this medicine after the expiry date which is stated on the bottle label and on the carton. Discard the bottle 28 days after opening, even if there is solution remaining.

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 [national name] contains

- The active substances are tobramycin and dexamethasone
- 1 ml solution contains 3 mg tobramycin and 1 mg dexamethasone.
- The other ingredients are benzalkonium chloride as a preservative, disodium edetate, hydroxyethylcellulose, water for injections, sodium chloride, sodium sulphate (E514), sulphuric acid (E513) and/or sodium hydroxide (E524), tyloxapol.

What [national name] looks like and contents of the pack

A plastic bottle containing 5 ml of a milky white suspension.

Marketing Authorisation Holder

[to be completed nationally]

Manufacturer

Tubilux Pharma S.p.A.

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