NOVARTIS

Information for patients
Read this leaflet carefully before using this medicine. This medicine has been prescribed for you personally. Do not pass it on to anyone else. It may harm them even if their symptoms are the same as yours.
Keep this leaflet. You may want to read it again later.

TobraDex®
eye drop suspension

What TobraDex eye drop suspension is and what it is used for
TobraDex eye drop suspension contains the active substances tobramycin (antibiotic) and dexamethasone (glucocorticoid with anti-inflammatory effect) and is intended for the treatment of certain types of eye inflammation with simultaneous bacterial eye infection.
TobraDex eye drop suspension requires a prescription that may be used once only and may only be used if it has been prescribed by a doctor.

Additional information to be aware of
You will require regular eye check-ups with your doctor throughout your treatment with TobraDex eye drop suspension.
The antibiotic contained in TobraDex eye drop suspension (tobramycin) is not effective against all microorganisms that cause eye infections. Using the wrong antibiotic or the wrong dose of antibiotic can cause complications. Therefore, never use this medicine to treat other conditions or other people. Even if you later develop a new infection, do not use TobraDex eye drop suspension without consulting your doctor again.

Do not use TobraDex eye drop suspension
TobraDex eye drop suspension must not be used in the following cases:
- If you have a known or suspected hypersensitivity (allergy) to any of the ingredients of TobraDex eye drops
- If you have glaucoma
- If you have an eye infection that cannot be treated with an antibiotic, e.g. certain viral diseases of the cornea and conjunctiva
- If you have tuberculosis of the eye
- If you have corneal ulcers or injuries (even after uncomplicated foreign body removal)
- If you have fungal eye diseases (mycoses) or untreated parasitic eye infections.

Warnings and precautions
- If you develop an allergic reaction such as eye itching, eyelid swelling or eye redness or generalised reactions such as skin redness, itching, raised, itchy bumps on the skin, anaphylaxis and blistering, stop treatment and consult your doctor. These allergic reactions may also occur with other (local or systemic) treatments with an antibiotic of the same type (aminoglycoside). If you are using other antibiotics together with TobraDex eye drop suspension, ask your doctor for advice.
- If you have or if you have ever had conditions such as myasthenia gravis or Parkinson's disease, ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness.
- There is a risk of fungal infection with prolonged use of TobraDex eye drop suspension.
- If you have eye infections with pus.
- Corticosteroids may mask, activate or worsen eye infections. Using TobraDex eye drop suspension for an extended period may lead to delayed wound healing. The pressure in the eye may also be increased, which may lead to glaucoma. You should be under constant medical supervision during treatment with TobraDex eye drop suspension and the pressure in your eye(s) should be checked regularly by a doctor.
- If the eye condition being treated with TobraDex eye drop suspension gets worse after 2-3 days of treatment or if new symptoms occur, consult your doctor immediately.
- If you suffer from diseases that cause thinning of the eye tissues (cornea or sclera), local corticosteroid use may cause perforation of the eye.
- If you have diabetes (particularly type I diabetes), you are at risk of developing a cataract. The use of corticosteroids by diabetics increases the risk of developing an early cataract that develops rapidly.
- If swelling occurs in your torso and face (Cushing's syndrome), tell your doctor. This risk is particularly significant in children and patients treated with ritonavir or cobicistat.
- TobraDex eye drop suspension contains benzalkonium chloride, a preservative that may cause eye irritation and that discolours soft contact lenses. Contact with soft contact lenses must be avoided. After you have applied TobraDex eye drop suspension, you must wait at least 15 minutes before reinserting your contact lenses.
- Benzalkonium chloride may also cause eye irritation, particularly if you have dry eyes or a disorder affecting the cornea (transparent layer on the front of the eye). Contact your doctor if you experience any unusual sensation, burning or pain in the eye after using this medicine.
- Caution is required when using TobraDex eye drop suspension at the same time as pupil-dilating medicines as an increase in eye pressure cannot be ruled out under these circumstances.
- The use and safety of TobraDex eye drop suspension in children and adolescents have not been studied. Therefore, the use of TobraDex eye drop suspension in children and adolescents is not recommended.
- Patients treated with more than one eye medicine must wait at least 5 minutes between the use of each product. Eye ointments should be used last.
- Tell your doctor or pharmacist if you have any other illnesses, have any allergies, are taking any other medicines (including non-prescription medicines) or applying any other medicines to your eye(s).
- As blurred vision may occur immediately after using TobraDex eye drop suspension, you should not drive or use machines after using this medicine until this effect has worn off.

Pregnancy and breast-feeding
TobraDex eye drop suspension is not recommended during pregnancy.
TobraDex eye drop suspension is not recommended during breast-feeding; therefore, you should either stop breast-feeding or stop using this medicine.

How to use TobraDex eye drop suspension
Dosage/Administration
Adults
The ophthalmologist (eye doctor) will determine the dosage individually for each patient. Always keep to the dosage prescribed for you by your doctor. Do not change the daily dose or the length of treatment without consulting your doctor. Do not interrupt treatment unless instructed by your doctor. If you experience swelling in your face or torso (Cushing's syndrome) and/or extreme weakness, nausea and persistent diarrhoea (symptoms of adrenal suppression), treatment should not be stopped abruptly. It should instead be gradually reduced – as agreed with your doctor – until treatment is stopped altogether.
If too much TobraDex eye drop suspension gets into your eye, rinse your eye with lukewarm water. Do not use any more drops until your next scheduled dose.
If you think the effect of your medicine is too weak or too strong, talk to your doctor or pharmacist.
Your doctor may prescribe TobraDex eye ointment as an additional treatment to TobraDex eye drop suspension (TobraDex eye ointment is mainly used as an overnight treatment at bedtime).

Children and adolescents
The use and safety of TobraDex eye drop suspension in children and adolescents have not been studied.

Possible side effects
You may experience the following side effects when using TobraDex eye drop suspension:

Uncommon (affects 1 to 10 in 1,000 users)
Increased pressure in the eye, eye pain, eye irritation, eye itching, eye discomfort.

Rare (affects 1 to 10 in 10,000 users)
Corneal inflammation, allergic reactions (e.g. eyelid itching or swelling), blurred vision, dry eye, eye redness, taste changes.
Consult your ophthalmologist (eye doctor) immediately if you experience such symptoms.

The following side effects were experienced after introduction to the market
Eyelid swelling or redness, dilated pupils, increased tear production, hypersensitivity, dizziness, headache, nausea, abdominal discomfort and rash, swollen face, itching, skin reactions (erythema multiforme).

Additional side effects of the individual active substances that may occur with TobraDex eye drops
Tobramycin
Corneal abrasion, reduced visual clarity, conjunctival swelling, eye discharge, skin inflammation, eyelash loss, lightening of skin, dry skin.

Dexamethasone
Conjunctival inflammation (conjunctivitis), visible defects due to corneal vital staining, sensitivity to light, foreign body sensation, abnormal sensation in the eye, eyelid margin crusting, irritation, glaucoma, corneal ulcer, reduced visual clarity, corneal erosion, eyelid drooping. Hormonal changes, e.g. increased body hair (particularly in women), muscle weakness and muscle wasting, stretch marks, high blood pressure, irregular or missed periods, change in the concentration of protein and calcium in the body, restricted growth in children and teenagers and swelling and weight gain affecting the torso and face (Cushing's syndrome).

Further information
Do not use after the expiry date marked with "EXP" on the container.
After treatment has ended, please return the bottle containing any remaining eye drops to the place you got it from (your doctor or pharmacist) so that it can be disposed of properly.
Your doctor or pharmacist will be able to give you more information. They have access to the full prescribing information.

Shelf life after opening
Once the bottle has been opened, use within 4 weeks

Storage instructions
Store the bottle upright, in the original pack, do not store above 30°C and out of the reach of children.

Additional information
Shake the bottle well before use. To avoid microbial contamination of the eye drops, do not allow the bottle's dropper tip to come into contact with your hands, eyes or any other object. Close the bottle immediately after use and always keep it tightly closed.
After opening the bottle, remove the loosened safety ring before using the drops.

What TobraDex eye drop suspension contains
Active substances
1 ml of eye drop suspension contains 1 mg of dexamethasone and 3.0 mg of tobramycin.

Other ingredients
This medicine contains 0.1 mg of benzalkonium chloride per 1 ml of solution. The other ingredients are tyloxapol, disodium edetate, sodium chloride, hydroxyethylcellulose, sodium sulphate, sulphuric acid and/or sodium hydroxide, and purified water.

Availability/pack sizes
The product can be obtained in pharmacies with a doctor's prescription, which may be used once.
Pack size: 5 ml dropper bottle.

Manufactured by
Alcon-Couvreur B-2870 Puurs (Belgium) for Novartis Pharma AG Basle, Switzerland.

This package leaflet was last reviewed by the Swiss Agency for Therapeutic Products (Swissmedic) in March 2020.

® = registered trademark
Novartis Pharma AG, Basle, Switzerland

This is a medicament
- A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists