

Package leaflet: Information for the patient

Truedex[®]

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

1. What Truedex is and what it is used for

Truedex 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 Truedex

Do not use Truedex:

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 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 nonsteroidal 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 Truedex, 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 Truedex, 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
- If you use Truedex for a long period of time, you may become more susceptible to eye infections, have increased pressure in your eye(s) or develop cataracts.
- If you are using other antibiotic treatment, including oral, with Truedex, ask your doctor for advice.
- 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 Truedex. 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 Truedex, 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 Truedex to children below 2 years old because the safety and efficacy in this population has not been established.

Other medicines and Truedex

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including 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 corneal healing problems. Tell your doctor if you are using ritonavir or cobicistat, 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 for advice before taking this medicine. Truedex is not recommended during pregnancy or breastfeeding.

Driving and using machines

If you experience temporary blurred vision after using Truedex 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. Truedex 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 Truedex

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

For topical ocular use.

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.

Use in children

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

Remove the loose collar from the cap when the bottle is first opened. Always use Truedex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Instructions for use

1. Before using the vial for the first time, make sure that the protective strip between the cap and the vial is not broken. Shake the vial vigorously. Wash your hands and unscrew the cap.
2. Tilt your head backwards and pull the lower eyelid down. This forms a “pocket” between the eyelid and the eye. The drop will go right here.
3. Keep the vial pointed downwards. Move the tip close to the eye. Use a mirror if it helps.
4. Do not touch your eye, eyelids or other surfaces with the tip of the vial. Press gently on the base of the bottle to release one drop of Truedex. Only light pressure on the bottom is required.
5. After instilling Truedex, close the lid and press the eye with a finger into the corner near the nose. This will help to stop Truedex from passing into the nose or running out.
6. If you have to use drops for both eyes, repeat the steps for the other eye.

If a drop misses your eye, try again.

Use this Truedex vial for your eyes only.

If you use more Truedex than you should

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

The following side effects have been seen with Truedex.

If you forget to use Truedex

Apply the drops as soon as you remember. If it is time for your next dose, continue with your regular schedule. Do not use a double dose to make up for a forgotten dose.

If you stop using Truedex

Even if your symptoms improve, do not stop using the eye drops unless your doctor has advised you to do so.

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

4. Possible side effects

Like all medicines, Truedex can cause side effects, although not everybody gets them. The following side effects have been seen with Truedex.

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 have also occurred with Truedex:

Uncommon side effects

(may affect up to 1 in 100 people)

Effects in the eye: increased pressure in your eye (s), 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, eyelid swelling, increased tear production,.

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

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").

If Truedex 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 to the «Scientific

Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan» CJSC
via www.pharm.am or call the hotline numbers: (+374 0) 20 05 05 and (+374 96) 22 05 05.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Truedex

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

Do not store above 25°C.

Store in the original package.

The shelf life after first opening of the vial is 28 days. Discard the bottle 4 weeks after opening to avoid any infection and contamination.

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

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 Truedex contains

- The active substances are tobramycin sulfate, equivalent to tobramycin 3 mg and dexamethasone 1 mg.
- The other ingredients are benzalkonium chloride, disodium edetate, sodium chloride, potassium dihydrogen phosphate, disodium phosphate dodecahydrate, polysorbate 80, hydroxyethylcellulose, water for injection.

What Truedex looks like and contents of the pack

White to pale yellow eye drops, suspension.

Sterile plastic vials with a volume of 5 ml, fitted with a dropper applicator and closed with a cap.

1 vial with a patient leaflet per carton.

Marketing Authorisation Holder

Pharmatech CJSC

111 Raffi str.

Yerevan, 0064, Armenia

Telephone: +374 10 741410

Fax: +374 10 734643

Manufacturer

Balkanpharma-Razgrad AD

68 Aprilsko Vastanie blvd.

7200 Razgrad

Bulgaria

This leaflet was last revised in 06/2021.