

PACKAGE LEAFLET: INFORMATION FOR THE USER

MAXIDEX

0.1% w/w eye ointment

DEXAMETHASONE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What MAXIDEX is and what it is used for
2. Before you take MAXIDEX
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1. WHAT MAXIDEX IS AND WHAT IS IT USED FOR

MAXIDEX belongs to a group of medicines X called corticosteroids.

It is used to treat allergy and inflammation of the eye.

It helps to relieve the symptoms of allergy and inflammation such as redness, soreness and swelling.

2. BEFORE YOU TAKE MAXIDEX

Do not use MAXIDEX

- If you think you have any type of infection, including viral and fungal infections and tuberculosis of the eye.
- If you are allergic to dexamethasone or any of the other ingredients listed in section 6. If any of these apply, ask your doctor for advice.

Take special care

- Only use MAXIDEX in your eye(s).
- MAXIDEX is not recommended for use in children under 2 years.

- Use of MAXIDEX for long periods of time, may cause increased pressure in your eye(s) and/or the development of cataracts. MAXIDEX should not be used for more than one week, unless advised by your doctor. The risk of corticosteroid-induced increase intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).
- If you already have high pressure in your eye(s) or an eye disease such as glaucoma, you should have your eye pressure checked regularly whilst using MAXIDEX. This is especially important in paediatric patients, as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults. Ask your doctor for advice especially in children.
- Use of steroids may make eye infections worse and delay healing of an eye wound. Topical NSAIDs (Non-Steroidal Anti Inflammatory Drugs-Medications) are also known to slow or delay healing. Using topical NSAIDs at the same time as topical steroids may increase corneal healing problems. If you are being treated or have been treated for viral herpes or any other eye infection, your eyes should be regularly examined by your doctor. If you have an infection, your doctor will prescribe another medicine to treat it.
- If you have a disorder causing a thinning of the eye tissues. Steroids may cause further thinning and possible perforation.
- Contact lens wear is not recommended during treatment of an ocular inflammation. If any of these apply, you may still be able to use MAXIDEX, but discuss it with your doctor first. Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Pregnancy and breast-feeding

If you are pregnant or might get pregnant or are breast feeding a baby, talk to your doctor before you use MAXIDEX. MAXIDEX should not be used during pregnancy or breast-feeding unless your doctor considers it necessary.

Driving and using machines

MAXIDEX may cause your vision to be blurred for some time after use. Do not drive or use machines unless your vision is clear.

Using other medicines

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 (Non-Steroidal Anti Inflammatory Drugs Medications). Using topical NSAIDs at the same time as topical steroids may increase corneal healing problems. If you are using more than one type of eye medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last.

3. HOW TO TAKE MAXIDEX

The usual dose

The usual dose for adults and children aged 2 years and above is to apply a small amount of MAXIDEX 3-4 times daily for 3-4 days or until a satisfactory response occurs.

If your symptoms get worse or suddenly return, please consult your doctor. You may be more likely to develop eye infections whilst using MAXIDEX.

Always use MAXIDEX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to use

Wash your hands before you start. Remove the cap from the tube. Tilt your head back. Pull down your lower eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The ointment will go inhere (picture 1). Bring the ointment tube close to the eye. Do this in front of a mirror if it helps.

Do not touch your eye or eyelid, surrounding areas or other surfaces with the tip of the tube. It could infect the ointment. Gently squeeze a small ribbon of ointment into the pocket formed between your lower eyelid and your eye (picture 2). Release the lower eyelid and blink a few times. If you use ointment in both eyes, repeat the steps for your other eye. Replace and tightly close the cap on the tube.



If the ointment misses your eye, try again.

If you forget to use MAXIDEX do not worry, just use it as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and go back to your normal dosing schedule. **Do not use a double dose to make up.**

If you use more MAXIDEX than you should it can be washed out of your eye with warm water.

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

4. POSSIBLE SIDE EFFECTS

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

You may experience some or all of the following effects in your eye(s) :

Common (affects 1 to 10 users in 100): discomfort.

Uncommon (affects 1 to 10 users in 1,000): swelling, dry eyes, sensitivity to light, blurred vision, abnormal sensation, increased tear production, eyelid crusting, itching, irritation, redness, foreign body sensation in the eye.

Not known (cannot be estimated from the available data): increased pressure in your eye(s), reduced vision, corneal disorder, drooping of eyelid, pain, increase in pupil size, cataract, perforation.

You may experience effects in other areas of your body including:

Uncommon: taste disturbance.

Not known: hypersensitivity reaction, dizziness, headache.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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

5. HOW TO STORE MAXIDEX

Keep out of the reach and sight of children.

Do not refrigerate or freeze or store above 25° C.

Do not use the ointment after the expiry date (marked 'Exp') on the tube and the carton. The expiry date refers to the last day of that month.

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

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Do not pass this medicine on to others.

It may harm them, even if their symptoms are the same as yours.

6. FURTHER INFORMATION

What MAXIDEX contains

The active substance is dexamethasone 1 mg /g (0.1 % w/w).

The other ingredients are anhydrous liquid lanolin, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and white soft paraffin.

What MAXIDEX looks like and contents of the pack

MAXIDEX is a colourless to slightly straw-coloured, slightly transparent ointment supplied in a pack containing a 3.5 g metal tube with a screw cap.

Manufacturer

SA Alcon-Couvreur NV, Rijksweg 14, B-2870 Puurs, Belgium.