

Package Leaflet - Information for the User

MAXIDEX[®] eye drops, suspension Dexamethasone

Read all of this leaflet carefully before you start using this medicine.

- **Keep this leaflet.** You may need to read it again.
- **If you have any further questions,** ask your doctor or your pharmacist.
- This medicine has been prescribed for you. **Do not pass it on to others.** It may harm them, even if their symptoms are the same as yours.
- **If any of the side effects get serious,** or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT MAXIDEX IS AND WHAT IT IS USED FOR

MAXIDEX belongs to a group of medicines known as corticosteroids.

It is used to treat inflammation of the eye surface and the front portion inside the eye (anterior segment) and to prevent or treat inflammation following surgery to the eye. It helps to relieve the symptoms of inflammation such as redness, soreness and swelling.

2. BEFORE YOU USE MAXIDEX

Do not use MAXIDEX...

- If you think that you have any **type of infection**, including viral, fungal, untreated parasitic eye 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 should be used **with caution in children under 2 years** of age.
- MAXIDEX should not be used for more than one week, unless advised by your doctor. Use of MAXIDEX for long periods of time, may cause:
 - Increased pressure in your eye(s). 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 while using MAXIDEX. Ask your doctor for advice. This is especially important in paediatric patients, as the risk of corticosteroid-induced increased pressure in the eye may be greater in children and may occur earlier than in adults. The risk of increase in eye pressure and/or cataract formation is higher in susceptible patients (e.g. patients with diabetes) using steroids.
 - The development of Cataracts. You should see your doctor regularly if using on a long term basis.

- Use of steroids **may make eye infections worse** and **delay healing** of an eye wound. If you have an infection, your doctor will prescribe another medicine to treat it. Topical NSAIDs (Non-Steroidal Anti Inflammatory Drugs-Medications) are also known to slow or delay healing. Simultaneous use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- If you have a disorder causing a **thinning of the eye tissues**. Steroids may cause further thinning and possible perforation.
- 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 MAXIDEX. 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.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Talk to your doctor before using MAXIDEX if you have diabetes or have a family history of diabetes

If any of these apply, you may still be able to use MAXIDEX, but discuss it with your doctor first.

Pregnancy and breast-feeding

If you are pregnant or might get pregnant, or if you are breast-feeding a baby, **talk to your doctor** before you use MAXIDEX.

MAXIDEX **should not be used** during pregnancy or breast-feeding.

Driving and using machines

MAXIDEX may cause your vision to be blurred for some time after use. **Do not drive or use any 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. Simultaneous use of topical steroids and topical NSAIDs may increase healing problems in your eye.

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

Tell your doctor if you are diabetic and you are taking, having recently taken or might take medicines for treatment of diabetes such as insulin, metformin or sulfonylureas such as chlorpropamide, as MAXIDEX may decrease the blood glucose lowering effect of these medicines.

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.

Important information if you wear Contact Lenses

Wearing contact lenses is **not recommended** while your eye is inflamed.

If you continue to wear your lenses, remove them before using MAXIDEX and wait at least **15 minutes** before putting your lenses back in.

There is a preservative in MAXIDEX (benzalkonium chloride) that may cause eye irritation and is also known to discolour soft contact lenses.

3. HOW TO USE MAXIDEX

The usual dose

The usual dose is 1 drop in the affected eye(s) every 4 hours.

However, in severe inflammations the dose may be increased to 1 to 2 drops every 30 to 60 minutes until a satisfactory response is obtained, when the dose may gradually be reduced.

Use MAXIDEX with caution **in children below 2 years** of age.

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

Remove the loose collar from the cap when the bottle is first opened.

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

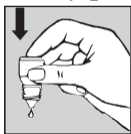
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How to use

- Wash your hands before you start.
- **Shake the bottle well.**
- Twist off the bottle cap.
- Hold the bottle pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).



- Bring the bottle tip 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 dropper. It could infect the drops.
- **Gently press on the base** of the bottle to release one drop at a time (picture 2).



- **Do not squeeze the bottle**, only a gentle press on the bottom is needed.
- After using MAXIDEX, press a finger into the corner of your eye by the nose (picture 3). This helps to stop the medicine getting into the rest of the body.



- If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.
- **If a drop misses your eye**, try again.
- **If you forget to take MAXIDEX**, do not worry, just take 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 take 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, corneal staining, sensitivity to light, blurred vision, abnormal sensation, increased tear production, eyelid crusting, itching, irritation or redness.

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

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

Uncommon: bad taste.

Not known: allergy, dizziness or headache, 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").

Steroids may be associated with an increase of blood glucose levels and diabetes.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. HOW TO STORE MAXIDEX

- Keep out of the reach and sight of children.
- Do not refrigerate, freeze or store above 25° C.
- Keep the bottle tightly closed.
- Store in the original package.
- Do not use the drops after the expiry date (marked 'Exp') on the bottle and the carton. The expiry date refers to the last day of that month.
- **Stop using the bottle 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/ml.
- The other ingredients are sodium chloride, disodium phosphate, citric acid, polysorbate 80, hypromellose, benzalkonium chloride, purified water and disodium edetate.

What MAXIDEX looks like and contents of the pack

MAXIDEX is a white to off-white suspension supplied in a pack containing a 8 ml or 10 ml plastic bottle with a screw cap.

Marketing authorisation holder:

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