

Package Leaflet - Information for the User

MAXIDEX® 0.1 %w/v eye drops, suspension 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 your 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 MAXIDEX is and what it is used for
2. What you need to know before you use MAXIDEX
3. How to use MAXIDEX
4. Possible side effects
5. How to store MAXIDEX
6. Contents of the pack and other information

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

2. What you need to know 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.

Warnings and Precautions

- Only use MAXIDEX in your eye(s).
- MAXIDEX is not recommended for use **in children under 2 years**.
- 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:
 - o **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.
 - o The development of **Cataracts**. You should see your doctor regularly if using on a long term basis.
 - o 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.

- 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 your doctor if you experience blurred vision or other visual disturbances.

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

Other medicines and Maxidex

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

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.

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 more than one type of eye medicine, the medicines must be used at least **5 minutes** apart. Eye ointments should be used last.

Pregnancy and 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 using this medicine. 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 any machines unless your vision is clear**

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.

Maxidex contains 0.5 mg of 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.

Maxidex contains 6.5 mg of phosphates in each 5 ml which is equivalent to 1.3 mg/ml.

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use MAXIDEX

The usual dose

The usual dose for adults and children aged 2 years and above is 1 drop in the affected eye(s) every 30-60 minutes for 3-4 days or until a satisfactory response occurs.

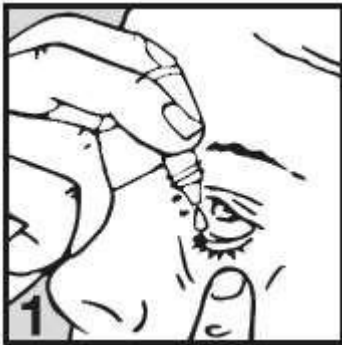
If your symptoms get worse or **suddenly return**, please consult your doctor. You may be more likely to develop eye infections while using MAXIDEX.

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

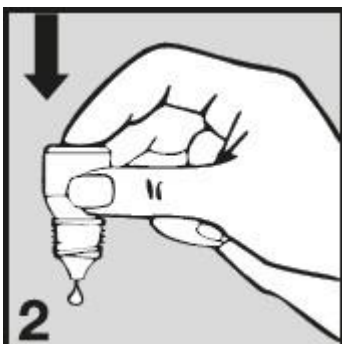
Always use MAXIDEX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to use

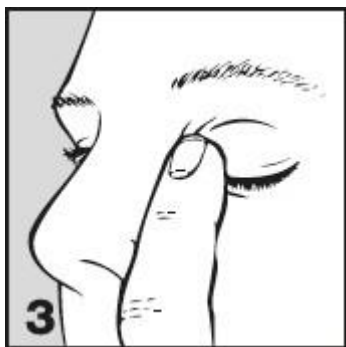
- Wash your hands before you start.
- **Shake the bottle well.**
- Twist off the bottle cap.
- Hold the bottle pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go 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) for 2 minutes. 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 eye staining,
- 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):

- glaucoma,
- corneal ulcer,
- increased pressure in your eye(s),
- reduced vision,
- corneal disorder,
- drooping of eyelid,
- pain,
- increase in pupil size,
- cataract,
- perforation.

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.

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

Uncommon:

- taste disturbance.

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”).

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. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie

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

5. How to store MAXIDEX

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

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

Keep the bottle tightly closed.

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.

Store in the original package.

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 to protect the environment.

6. Contents of the pack and other information

What MAXIDEX contains

- The active substance is dexamethasone 1 mg /ml (0.1 % w /v).
- The other ingredients are sodium chloride, disodium phosphate, citric acid monohydrate (for pH adjustment), polysorbate 80, hypromellose, Disodium edetate, benzalkonium chloride and purified water.

What MAXIDEX looks like and contents of the pack

MAXIDEX is a white to off-white suspension supplied in a pack with a plastic bottle with a screw cap containing 5 ml or 10 ml of eye drops suspension.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Novartis Ireland Ltd.
Vista Building
Elm Park
Merrion Road
Ballsbridge
Dublin 4
Ireland

Manufacturer

Novartis Farmacéutica, S.A.
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08013 Barcelona
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