

MAXIDEX™ Eye Ointment 0.1%

Dexamethasone

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Read this leaflet carefully before you start to use Maxidex Eye Ointment.

This leaflet answers some common questions about Maxidex Eye Ointment. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from
www.medsafe.govt.nz.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Maxidex against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Maxidex is used for

Maxidex contains dexamethasone which is a type of cortisone. It belongs to the group of medicines called corticosteroids.

Maxidex is used to treat:

- the redness, swelling and other symptoms due to inflammation or allergy of the eye
- injury of the cornea caused by chemical, heat burns or foreign bodies.

Before prescribing Maxidex Eye Ointment for you, your doctor will have examined your eye(s) and decided that Maxidex Eye Ointment is the right medicine for you.

Your doctor may have prescribed Maxidex for another purpose.

Ask your doctor if you have any questions about why Maxidex has been prescribed for you.

Maxidex is not addictive.

This medicine is available only with a doctor's prescription.

Use in children

Maxidex is not for use in children. The safety and effectiveness of Maxidex in children has not been established.

Before you use Maxidex

When you must not use it

Do not use Maxidex if you have an allergy to:

- dexamethasone or any of the ingredients listed at the end of this leaflet under "Product description"
- any other corticosteroid medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use Maxidex Eye Ointment if:

- **the packaging is torn or shows signs of tampering.**
- **the expiry date (EXP) printed on the pack has passed.**

If you use Maxidex after the expiry date has passed, it may not work.

Do not put the eye ointment into your eye(s) while you are wearing soft contact lenses.

Do not use Maxidex Eye Ointment if you have an eye infection including:

- a viral infection
- a bacterial infection
- a fungal infection
- a parasitic infection
- tuberculosis of the eye.

If you are not sure whether you should start using Maxidex Eye Ointment, talk to your doctor.

Before you start to use it

Tell your doctor if:

- **you have allergies to any other medicines or any substances such as foods, preservatives or dyes**
- **you are pregnant or intend to become pregnant**

Maxidex is not recommended in pregnant women. Your doctor will discuss the risks and benefits of using Maxidex Eye Ointment when pregnant.

- **you are breastfeeding or intend to breastfeed.**

Your doctor will discuss the risks and benefits of using Maxidex Eye Ointment when breastfeeding.

Tell your doctor if you have the following medical conditions:

- Sjogren's keratoconjunctivitis
- History of glaucoma, high myopia or family history of these conditions

- Patients prone to increase in the pressure in the eye e.g. in diabetes
- Patients with infections due to a bacteria, virus, fungus or a parasite.

This medication may mask these infections or suppress the immune system leading to further infections of the eye.

- Diseases that cause thinning of the cornea or sclera.

If you have not told your doctor about any of the above, tell them before you start to use Maxidex Eye Ointment.

Using or taking other medicines

Tell your doctor or pharmacist if you are using other eye drops, ointments or taking any other medicines. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are using or taking the following medicines:

- Other corticosteroids or steroid medicines
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
- Medicines used to treat viral infections e.g. ritonavir or cobicistat
- Anticholinergic drugs such as atropine.

These medicines may be affected by Maxidex or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines. Your doctor and

pharmacist have more information on medicines to be careful with or avoid while using this medication.

How to use Maxidex

How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

The dosing instructions will be printed on the label that your pharmacist puts on the bottle or carton.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to use

The dose of Maxidex will depend on the severity of your condition. Your doctor may recommend that you apply a **half-inch (1 - 1.5 cm) ribbon** to the affected area up to four times daily.

When a favourable response is observed the doctor will advise you to reduce the dosage gradually to once daily application for several days.

How to use

It is important to use Maxidex exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and your eye problem may not improve. Using it more often than you should may not improve your eye problem any faster and may cause side effects.

Follow these steps to use Maxidex:

1. Wash your hands thoroughly.
2. Remove the cap from the tube. Using your forefinger, gently pull your lower eyelid down to form a pouch (see Diagram 1).



Diagram 1

3. Using your other hand, carefully squeeze a small ribbon (about 1 – 1.5 cm) of ointment into the pouch (see Diagram 2).



Diagram 2

4. Making sure that the ointment remains within the eye, slowly close your eye without blinking (see Diagrams 3 and 4). Keep your eye closed for 1 to 2 minutes.



Diagrams 3



Diagrams 4

5. If necessary, repeat the above steps 1-4 for your other eye.
6. Place the cap on the tube and close it tightly.
7. Wash hands again with soap and water to remove any residue.

You may feel a slight burning sensation in the eye shortly after using Maxidex Eye Ointment. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the tip of the tube against your fingers or the eye, or anything else.

This will help prevent the ointment becoming dirty or contaminated.

When using more than one eye care product, wait at least 5 minutes before using the next product on your eye. Ointments should be administered last.

How long to use it

Your doctor or pharmacist will tell you how long to use Maxidex.

Do not use Maxidex for longer than your doctor tells you.

If you use Maxidex for longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are not sure how long to use Maxidex, talk to your doctor or pharmacist.

If you forget to use it

If you forget to use Maxidex you should use the ointment as soon as you remember, and then use your next dose as recommended by your doctor.

If it is almost time for your next dose, skip the dose you missed and continue using them as recommended.

Do not use a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you think that you or someone else has swallowed any or all of the contents of Maxidex Eye Ointment, or used too much ointment, immediately telephone your doctor, or the National Poisons Centre on 0800 POISON or 0800 764 766 or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using Maxidex

Things you must do

If you are about to be started on any medicine, remind your

doctor and pharmacist that you are using Maxidex.

Tell any other doctors, dentists and pharmacists who are treating you that you are using Maxidex.

If you feel that Maxidex is not helping your condition, tell your doctor (or pharmacist).

Keep all your doctor's appointments so that your progress can be checked.

Tell your doctor if, for any reason, you have not used Maxidex exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you experience swelling and weight gain around the trunk and in the face, it may be symptoms of a hormonal imbalance known as Cushing's syndrome. Talk to your doctor before stopping the treatment by yourself. Stopping long term or intensive treatment with Maxidex may cause your adrenal glands to not work properly. These risks are especially important in children and patients treated with medicine containing ritonavir or cobicistat.

Tell your doctor immediately if you become pregnant while using Maxidex.

Things you must not do

Do not stop using Maxidex without first asking your doctor.

Do not use Maxidex to treat other complaints unless your doctor or pharmacist tells you to.

Do not give Maxidex to anyone else, even if they have the same symptoms as yours.

Do not let children handle Maxidex.

Do not wear contact lenses while you are using Maxidex.

Things to be careful of

You should not drive or operate any machinery if Maxidex affects your vision (blurred vision).

Ask your doctor or pharmacist if you are concerned about the length of time you have been using Maxidex.

Side effects

Tell your doctor as soon as possible if you do not feel well while using Maxidex.

This medicine helps most people with treating eye inflammation but it may have unwanted effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and the worry you:

Reactions that affect the eyes have been reported including:

- glaucoma

Some of the symptoms of glaucoma include pain, discomfort, irritable or redness of the eye, change in vision, seeing "halos" or sensitivity to light.

Your doctor will need to check your eyes to determine if you have glaucoma.

- eye discomfort, grittiness, itchiness, irritation, pain

- dry eye or watery eyes
- red eye
- blurred vision
- inflammation of eye
- secondary eye infection
- staining front part of the eye
- drooping eyelid
- crustiness of eyelid
- dilated pupil
- sensitivity to sunlight
- corneal erosion (front part of the eye shedding abnormally)

Occasionally some people notice unwanted effects in the rest of their body as a result of using Maxidex Eye Ointment. These effects may include:

- allergy
- bad taste in the mouth
- dizziness
- headache
- hormonal imbalance (higher or lower than normal levels).
- 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')

Tell your doctor immediately and stop using Maxidex at the first sign

of a skin rash or any other sign of allergy (e.g. hives).

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell while using Maxidex.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Maxidex

Storage

Keep Maxidex in a cool dry place where the temperature stays at or below 25°C. Do not refrigerate Maxidex.

Do not store Maxidex or any other medicine in the bathroom or near a sink. Do not use it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Maxidex in a safe place away from the sight or reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Write the date on the carton when you first start to use the ointment and throw away any remaining amount after 4 weeks.

If your doctor tells you to stop using Maxidex or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Maxidex Eye Ointment comes in a 3.5g tube with screw cap.

Ingredients

The active ingredient in Maxidex Eye Ointment is dexamethasone 1 mg in 1 g.

Maxidex Eye Ointment also contains:

- Methyl hydroxybenzoate
- Propyl hydroxybenzoate
- Lanolin oil
- White soft paraffin.

Supplier

Maxidex is supplied in New Zealand by:

Novartis New Zealand Limited

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335

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