

MAXIDEX® Eye Drops 0.1%

Dexamethasone

Consumer Medicine Information

What is in this leaflet

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

This leaflet answers some common questions about Maxidex Eye Drops. 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.novartis.com.au

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 Drops for you, your doctor will have examined your eye(s) and decided that Maxidex Eye Drops 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 Drops if:

- **the safety seal around the closure and neck area is broken**
- **the bottle/packaging shows signs of tampering**
- **the expiry date on the bottle/carton has passed.**
If you use this medicine after the expiry date has passed, it may not work.

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

The preservative in Maxidex Eye Drops, benzalkonium chloride, may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used Maxidex Eye Drops.

Do not use Maxidex Eye drops 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 Drops, 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 Drops when pregnant.

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

Your doctor will discuss the risks and benefits of using Maxidex Eye Drops 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
- Prone to increase in the pressure in the eye e.g. in diabetes
- An infection 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 him/her before you start to use Maxidex Eye Drops.

Using other medicines

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

Tell your doctor if you are using 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.

If your condition is severe, the usual dose of Maxidex is one to two drops in the affected eye(s) every hour.

The number of times that you will need to use Maxidex will decrease as the inflammation settles before finally stopping the eye drops.

If your condition is mild, the usual dose of Maxidex is one to two drops in the affected eye(s) up to four to six times a day.

How to use it

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.

Do not touch the tip of the dropper tip with your fingers, to the eye or any other surface. This will help prevent the eye drops becoming dirty or contaminated.

If you wear soft contact lenses, remove your contact lenses before using this medicine. Wait for 15 minutes after using it before reinserting your contact lenses into your eyes.

Follow these steps to use Maxidex:

1. Wash your hands thoroughly
2. Shake the bottle well before using
3. Remove the cap from the bottle.
4. Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away
5. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

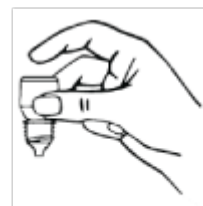


Diagram 1

6. Tilt your head back and look up.
7. Using your other hand, gently pull down the lower eyelid to form a pouch or pocket.
8. Put the tip of the dropper close to, but not touching your eye. Release the required number of drops into the pouch/pocket formed between the eye and eyelid by gently squeezing the side of the bottle (see Diagrams 2 and 3).

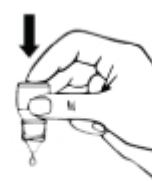


Diagram 2



Diagram 3

9. Close the eye gently and press on the inside corner of the eye with the pad of your index finger for 2 minutes.
10. If necessary repeat the above steps 5-9 for your other eye.
11. Replace the cap on the bottle, closing it tightly.
12. Wash your hands again with soap and water to remove any residue.

After using Maxidex wait at least 5 minutes before putting any other eye drops in your eye(s). 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 put the drops that you missed in the eye(s) as soon as you remember, and then go back to using them 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.

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

If you use too much (overdose)

If you accidentally put too many drops in your eye(s) immediately rinse your eye(s) with warm water.

Immediately telephone your doctor or the nearest Poisons Information Centre on 13 11 26 or go to Accident and Emergency at the nearest hospital, if you think that you or someone else has swallowed Maxidex. 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.

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:

- **Glaucoma.**
Some of the symptoms of glaucoma include pain, discomfort, irritability 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 or watery eyes
- red eye
- blurred vision
- inflammation of the 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 Drops. 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 below 25°C.

Do not freeze Maxidex.

Do not store Maxidex or any other medicine in the bathroom or near a sink. Do not leave 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.

Put the top back on the bottle right away after use to avoid contamination.

Disposal

Write the date on the bottle when you open the eye drops and throw away any remaining solution after 4 weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle.

After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should then be used.

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 is a white to pale yellow, opaque suspension that comes in a 5mL plastic dropper bottle.

Ingredients

The active ingredient in Maxidex Eye Drops is dexamethasone 1 mg in 1 mL.

Maxidex Eye Drops also contain:

- Benzalkonium chloride as a preservative
- Dibasic anhydrous sodium phosphate
- Polysorbate 80 (Tween 80)
- Disodium edetate
- Sodium chloride
- Hypromellose
- Citric acid monohydrate and/or sodium hydroxide use to adjust pH
- Purified water.

Allergen:

May contain sulfites.

Supplier

Maxidex is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
 ABN 18 004 244 160
 54 Waterloo Road
 Macquarie Park NSW 2113
 Telephone: 1-800-671-203.
 Web site: www.novartis.com.au

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