Maxidex®

Eye Drops

Dexamethasone

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Maxidex?

Maxidex contains the active ingredient Dexamethasone. Maxidex is used to treat certain inflammatory eye conditions and injury of the cornea caused by chemical, heat burns or foreign bodies.

For more information, see Section 1. Why am I using Maxidex? in the full CMI.

2. What should I know before I use Maxidex?

Do not use if you have ever had an allergic reaction to Maxidex or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Maxidex? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Maxidex and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Maxidex?

- Follow the instructions carefully provided by your doctor.
- Use one or two drops in the affected eye(s) as prescribed by your doctor.

More instructions can be found in Section 4. How do I use Maxidex? in the full CMI.

5. What should I know while using Maxidex?

Things you should do	• Remind any doctor, dentist, pharmacist or specialist you visit that you are using Maxidex. • Remove soft contact lenses before using Maxidex. • Tell your doctor immediately if you develop any signs of allergic reaction.
Things you should not do	• Do not stop using this medicine suddenly. • Do not use it in children and elderly patients. • Do not give Maxidex to anyone else, even if they seem to have the same condition as you.
Driving or using machines	• Maxidex may cause temporary blurred vision or other vision problems in some people and may affect the ability to drive or use machines. • If blurred vision occurs after use, wait until your vision clears before driving or using machinery.
Looking after your medicine	• Store below 25 °C • Do not freeze.

For more information, see Section 5. What should I know while using Maxidex? in the full CMI.

6. Are there any side effects?

Common side effects include discomfort in eye(s), feeling that something is in your eye(s), excessive secretion of tears from the eye(s), blurred vision, increased sensitivity to light, eye irritation.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Maxidex®

Eye Drops

Active ingredient: *Dexamethasone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Maxidex. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Maxidex.**

Where to find information in this leaflet:

1. Why am I using Maxidex?
2. What should I know before I use Maxidex?
3. What if I am taking other medicines?
4. How do I use Maxidex?
5. What should I know while using Maxidex?
6. Are there any side effects?
7. Product details

1. Why am I using Maxidex?

Maxidex contains the active ingredient Dexamethasone. Maxidex belongs to the group of medicines called corticosteroids.

Maxidex is used to treat certain inflammatory conditions and injury of the cornea caused by chemical, heat burns or foreign bodies. It helps in reducing swelling and relieves symptoms such as redness and soreness of eyes.

2. What should I know before I use Maxidex?

Warnings

Do not use Maxidex:

- If you are allergic to Dexamethasone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of an allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- If the safety seal around the closure and neck area is broken or if the bottle/packaging shows signs of tampering
- In children and elderly patients
- If you suffer from:
- Any viral infections of eyes, symptoms such as eye pain, blurred vision, redness, light sensitivity, irritation
- Tuberculosis of the eye, symptoms include eye redness, eye pain, headache, blurred vision
- Fungal eye diseases, symptoms include watery eyes, redness, eye discomfort, itching, irritation, eye pain
- Untreated parasitic eye infections, symptoms include vision problems, foreign body sensation, eye swelling
- Mycobacterial eye infections, symptoms include eye discharge, sensitivity to light, blurred vision
- Untreated bacterial eye infections, symptoms include excessive tearing, blurred vision, sensitivity to light.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- suffer from symptoms such as dry eye, eye pain, vision problems and problems with cornea
- have a family or personal history of glaucoma (an eye condition that damages the optic nerve) or high myopia (severe nearsightedness)
- have diabetes
- suffer from any liver or kidney problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Maxidex is not recommended in pregnant women.

Your doctor will advise you regarding the possible risks and benefits of using Maxidex during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will advise you regarding the possible risks and benefits of using Maxidex during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Maxidex and affect how it works.

- Tell your doctor if you take any of the following medicines:
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), e.g. salicylates, ibuprofen or aspirin.
- Other corticosteroids or steroid medicines
- Ritonavir or cobicistat, drugs used to treat viral infections
- Anticholinergic medicines e.g. atropine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Maxidex.

4. How do I use Maxidex?

How much to use

- Follow the instructions provided and use Maxidex until your doctor tells you to stop.
- Use one or two drops topically in the conjunctival sac(s) as prescribed by your doctor.
- The dose of Maxidex depends on the severity of your condition. In severe diseases, your doctor may advise you to use the drops hourly.
- In mild diseases, your doctor may advise you to use drops up to four to six times daily.
- **If you do not understand your dose, contact your doctor or pharmacist.**

When to use Maxidex

- Maxidex should be used as prescribed by your doctor.

How to use Maxidex

- Sitting or lying down position might make the process simpler.
- Remove contact lenses if you are wearing them before using the eye drops.
- Shake the bottle well prior to use.
- **Follow the steps below to use Maxidex:**
- Wash your hands thoroughly with soap and water.
- Before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- Remove the cap from the bottle.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Hold the bottle upside down in one hand between your thumb and middle finger (refer diagram 1).

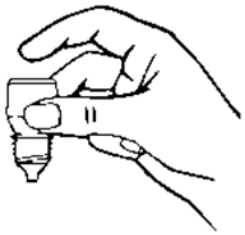

Diagram 1

- Tilt your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
- Place the tip of the bottle close to your eye. Do not touch the tip to your eye as this may cause injury to the eye.
- Do not touch the dropper tip to your eyelid or surrounding areas or any surface to avoid contamination of the dropper tip and solution.
- Release the required number of drops as advised by your doctor into the pouch/pocket formed between the eye and eyelid gently tapping or pressing the base of the bottle with your forefinger (refer diagrams 2 and 3).

Diagram 2

Diagram 3

- Gently close your eyes. Do not blink or rub your eye(s).
- When your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to prevent the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body and may result in less side effects.
- If necessary, repeat the above steps for the other eye.
- If you want to use any other eye drops, wait at least 5 minutes after using Maxidex. Eye ointments should be used last.
- It is normal for a small amount of eye drops to spill onto your cheek since your eyelid can only hold less than one drop at a time. Wipe away any spillage with a tissue.
- Replace the cap on the bottle and close it tightly.
- Always keep the bottle tightly closed when not in use.
- Wash your hands again with soap and water to remove any residue.
- Wait for 15 minutes before putting your contact lenses in.
- Discard Maxidex Eye Drops 4 weeks after opening it.

If you forget to use Maxidex

Maxidex should be used as prescribed by your doctor. If you miss your dose at the usual time, put the drops that you missed in your eye(s) as soon as you remember, and then go back to using them as advised by your doctor.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Maxidex

If you think that you have used too much Maxidex, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you accidentally use several Maxidex Eye Drops in your eyes, immediately wash your eyes with lukewarm water.

5. What should I know while using Maxidex?

Things you should do

- Maxidex Eye Drops are for eye use only.
- Do not put Maxidex into your eye(s) while wearing contact lenses.
- Remove soft contact lenses before using Maxidex.
- Benzalkonium chloride, one of the ingredients in Maxidex may cause eye irritation and is known to discolour soft contact lenses.
- Put your lenses back in 15 minutes after using the eye drops.

Call your doctor straight away if you:

- notice any signs of allergic reaction.
- develop symptoms such as blurred vision or other vision problems.
- become pregnant, plan to become pregnant or if you are breast feeding while using Maxidex.
- notice any symptoms of infection in your eye(s) such as eye redness, eye pain, sensitivity of light. Maxidex may mask infections and prolong use may suppress the immune system leading to further infections of the eye.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Maxidex.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not give Maxidex to anyone else, even if they seem to have the same condition as you.
- Do not touch the dropper tip to your eyelids, surrounding areas or any other surfaces.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Maxidex affects you.

Maxidex may cause temporary blurred vision or other vision problems in some people and may affect the ability to drive or use machines.

If blurred vision occurs after use, wait until your vision clears before driving or using machinery.

Looking after your medicine

- Store below 25°C
- Do not Freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard Maxidex Eye Drops 4 weeks after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Eye problems: • Discomfort in eye(s) • Increased sensitivity to light • Blurred vision • Itching in eye(s) • Feeling that something is in your eye(s) • Excessive secretion of tears from the eye(s) • Abnormal sensation in eye • Eye irritation • Eye pain • Redness of the eye(s) • Crustiness of eyelid(s) **Other problems:** • Dizziness • Headache	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Eye problems: • Increase in eye pressure **Other problems:** • Taste disturbance or loss of taste • Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives **Hormone problems:** • Symptoms such as weight gain of the body and face, muscle weakness, acne, pink or purple stretch marks on stomach, hips, thighs, breasts and underarms (called 'Cushing's syndrome') • Extreme tiredness, muscle weakness, irritability, weight loss, feeling sick.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Maxidex contains

Active ingredient (main ingredient)	1 mg/mL dexamethasone
Other ingredients (inactive ingredients)	dibasic anhydrous sodium phosphate, polysorbate 80 (Tween 80), disodium edetate, sodium chloride, hypromellose and purified water. Citric acid monohydate and/or sodium hydroxide are used to adjust the pH. The suspension is preserved with benzalkonium chloride (0.1 mg/mL).
Potential allergens	May contain sulfites from the manufacturing process.

Do not take this medicine if you are allergic to any of these ingredients.

What Maxidex looks like

Maxidex is white to pale yellow, opaque suspension with no agglomerates and is supplied in a 5 mL LDPE bottle with a LDPE plug and PP closure.

Australian registration number

AUST R: 25354

Who distributes Maxidex

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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