

MAXIDEX EYE DROPS

Dexamethasone (1mg/ml)

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What MAXIDEX is used for

Maxidex is used to treat:

- inflammation or allergy of the eye
- injury of the cornea caused by chemical or heat burns

How MAXIDEX works

Maxidex is a corticosteroid. It reduces the redness, swelling and other inflammatory symptoms.

Before you use MAXIDEX

- When you must not use it

Do not use Maxidex:

- If you are allergic to dexamethasone or any of the other ingredients of this medicine
- If you have or you think you have an eye infection including:
 - bacterial infection
 - viral infection
 - fungal infection
 - parasitic infection
 - tuberculosis of the eye

The safety and efficacy of MAXIDEX in children and people with liver or kidney impairment have not been established.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Maxidex is not recommended during pregnancy or breastfeeding.

- Before you start to use it

Maxidex contains benzalkonium chloride. Wearing contact lenses is not advisable during treatment of an eye inflammation as it may make your condition worse. A preservative in Maxidex (benzalkonium chloride) may cause eye irritation and is also known to discolor soft contact lenses. If your healthcare provider considers that you can use contact lenses, you should remove them before using Maxidex and wait at least 15 minutes before putting your lenses back in.

Consult your doctor or pharmacist if you have a disorder causing thinning of the eye tissues before using this medicine.

- Taking other medicines

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

Tell your doctor if you are using topical NSAIDs (Non-Steroidal Anti Inflammatory Drugs-Medications). Concomitant use of topical steroids and topical NSAIDs may increase corneal healing problems.

Tell your doctor if you are using ritonavir or cobicistat (medicines for

HIV), as this may increase the amount of dexamethasone in the blood.

How to use MAXIDEX

- How much to use

Instill 1 or 2 drops in the eye.

Severe or acute inflammation: Instill every 30 to 60 minutes as initial therapy, reducing the dosage when favourable response is observed to every 2 to 4 hours. Further reduction may be made to 1 drop 3 or 4 times daily if sufficient to control inflammation.

Chronic inflammation: Instill every 3 to 6 hours, or as frequently as necessary.

Allergies or minor inflammation: Instill every 3 to 4 hours until the desired response is obtained.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Maxidex for as long as your doctor recommends.

- If you forget to use it

If you forget to use Maxidex, continue with the next dose as planned. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to make up.

- If you use too much (overdose)

Rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

While you are using MAXIDEX

- Things you must do

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Only use Maxidex for dropping in your eye(s).

Shake the bottle well before use.

Keep the eyelid closed, while simultaneously applying gentle pressure to the inner corner of the eye with a finger to limit the amount of medicine that will come into the blood after application of the eye drops.

If you are using other eye drop or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

After cap is removed, if tamper evident snap collar is loose, remove before using product.

If you use Maxidex for a long period of time, you may:

- have increased pressure in your eye(s). You should have your eye pressure checked regularly while using Maxidex. Ask your doctor for advice. This is especially important in children, as the risk of corticosteroid-induced increase pressure in the eye may be greater in children and may occur earlier than in adults. Maxidex is not approved for use in children. The risk is increased in people with diabetes.
- Develop a cataract. You should see your doctor regularly if using on a long term basis.
- Develop Cushing's Syndrome due to the medicine getting into

your blood. 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 the 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 people treated with medicines containing ritonavir or cobicistat.

If your symptoms get worse or suddenly return, please contact your doctor. You may become more susceptible to eye infections with the use of this product.

If you have an infection, your doctor will prescribe another medicine to treat that infection.

Steroids applied to the eye may delay the healing of your eye wound.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

- Things to be careful of

You may find your vision is blurred for a time after you use Maxidex. Do not drive or use machines until this has worn off.

Do not let the tip of the dropper touch the eye.

Side effects of MAXIDEX

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been seen with Maxidex:

Common side effects (may affect up to 1 in 10 people)

- Effects in the eye: eye discomfort

Uncommon side effects (may affect up to 1 in 100 people)

- Effects in the eye: eye surface inflammation, dry eye, corneal staining, sensitivity to light, blurred vision, abnormal sensation in the eye, increased tear production, eyelid crusting, itchy eye, eye irritation or redness.
- General side effects: bad taste

Additional side effects from post-marketing experience that have been reported for which the frequency is not known:

- Effects in the eye: corneal ulcer, increased pressure in your eye(s), reduced vision clarity, corneal erosion (front part of the eye shredding abnormally), drooping of eyelid, eye pain, increase in pupil size.
- General side effects: 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 the children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome'); allergy, dizziness, headache.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of MAXIDEX

- Storage

Store below 30°C.

Store the bottle upright.

Keep the bottle tightly closed.

Do not use this medicine after the expiry date which is stated on the packaging.

Discard 4 weeks after first opening.

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

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Maxidex is an opaque, white to pale yellow suspension and no agglomerates. It is supplied in a 5ml sterile dispenser.

- Ingredients

- Active ingredient(s)

1ml of suspension contains 1 mg dexamethasone.

- Inactive ingredients

Disodium phosphate, polysorbate 80, disodium edetate, sodium chloride, citric acid monohydrate and/or sodium hydroxide (to adjust pH), benzalkonium chloride, hydroxypropyl methylcellulose and purified water.

- MAL number:

MAL19890182ARZ

Manufacturer

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Product Registration Holder

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