NOVARTIS

MAXIDEX® Eye Drops

(dexamethasone)

Eye Drops, 1 mg / ml

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

Scheduling Status S4

MAXIDEX® Eye Drops, 1 mg / ml

Dexamethasone

Read all of this leaflet carefully before you start using MAXIDEX®

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- MAXIDEX® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the as yours.

What is in the leaflet

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 inflammation of the eye surface and the front portion inside the eye (anterior segment) and to prevent inflammation following surgery to 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 are hypersensitive (allergic) to dexamethasone or any of the other ingredients of MAXIDEX® (listed in section 6)
- If you think you have any type of infection, including viral, fungal, untreated parasitic eye infections and tuberculosis of the eye.

Warnings and precautions

Take special care with MAXIDEX®

- MAXIDEX® should not be used for longer than one week, unless advised by your doctor. If you use MAXIDEX® for a long period of time, you may:
  - Have increased pressure in your eye(s). You should have your eye 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 increased in predisposed patients (e.g. patients with diabetes).
  - Develop cataracts. 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 on the face as these are usually the first manifestations of the 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 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. Medicines containing topical NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- Consult your doctor or pharmacist if you have a disorder causing thinning of the eye tissues before this medicine. Steroids may cause further thinning and possible perforation.

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.

Children and adolescents

The safety and efficacy of this product has not been established in children.

Other medicines and MAXIDEX®

Always tell your health care provider if you are taking any other medicine. This includes all complementary or traditional medicines.

Tell your doctor if you are using topical NSAIDs. Simultaneous use of topical steroids and topical NSAIDs may increase healing problems in your eye.

Tell your doctor if you are ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.

Tell your doctor if you are diabetic and you are taking, having recently taken or might take medicines for treatment of diabetes such as insulin, metformin or sulfonylureas such as chlorpropamide, as MAXIDEX® may decrease the blood glucose lowering effect of these medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

MAXIDEX® is not recommended during pregnancy or breastfeeding.

Driving and using machines

MAXIDEX® may cause your vision to be blurred for some time after use. Do not drive or use machines unless your vision is clear.

MAXIDEX® contains benzalkonium chloride

There is a preservative in MAXIDEX® which is called benzalkonium chloride that may cause eye irritation and is also known to discolour soft contact lenses.

MAXIDEX® contains sodium phosphate

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®

Only use for dropping in your eyes

Do not share medicines prescribed for you with any other person.

Always use MAXIDEX® exactly as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 1 or 2 drops into the affected eye(s) 4 to 6 times daily.

In severe inflammation, the dose may be increased instillations every 60 minutes until a satisfactory response is obtained, when the dose may gradually be reduced.

Your doctor will tell you how long your treatment with MAXIDEX® will last. Do not stop treatment early. If you have the impression that the effect of MAXIDEX® is too strong or too weak, tell your doctor, pharmacist or nurse.

- SHAKE THE BOTTLE WELL BEFORE USE
- Twist off the bottle cap is removed, if tamper evident snap collar is loose, remove before using the product.
- Only use MAXIDEX® for dropping into your eye(s).

- Keep the eyelid closed, while simultaneously applying gentle pressure to the lachrymal duct (tear duct) with a finger to limit the amount of medicine that will come into the blood after application of the eye drops.
- If a drop misses your eye, try again.
- 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 take more MAXIDEX® than you should

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

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

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

4. Possible side effects

MAXIDEX® can have side effects.

Not all side effects reports MAXIDEX® are included in this leaflet. Should your general health worsen or if you experience and untoward effects while taking MAXIDEX®, please consult your health care provider for advice.

Like all medicines, MAXIDEX® can cause side effects, although not everybody gets them. The following side effects have been seen MAXIDEX®:

Uncommon side effects (may occur in 1 to 10 users in 1 000):

- Effects in the eye: eye surface inflammation, increased eye pressure, itchy eye, eye discomfort, eye irritation

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

- Effects on the eye:
  - Corneal ulcer
  - Blurred vision
  - Sensitivity to light
  - Increase in pupil size
  - Drooping of eyelid
  - Eye pain
  - Eye swelling
  - Abnormal sensation in the eye
  - Redness
  - Increased tear production

- General side effects:
  - Allergy
  - Headache

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MAXIDEX®.

5. How to store MAXIDEX®

- Store all medicines out of reach of children
- Store at or below 25 °C
- Protect from light and moisture
- Do not store in the bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- Do not use more than 28 days after opening
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicines in drains or sewerage system

6. Contents of the pack and other information

What MAXIDEX® contains

The active substance is dexamethasone 1,0 mg/ml

The other ingredients are sodium phosphate, polysorbate 80, disodium edetate, sodium chloride, benzalkonium chloride, hypromellose, citric acid, purified water.

What MAXIDEX® looks like and contents of the pack

What MAXIDEX® looks like:

- MAXIDEX® is a white to pale yellow, opaque sterile suspension.

Contents of the pack:

- A natural, low-density polyethylene bottle with white closure, containing 5 ml.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

2090

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