

CONSUMER INFORMATION

Pr MAXIDEX®
Dexamethasone Ophthalmic Ointment

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MAXIDEX®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

MAXIDEX is used to treat eye inflammation and eye injuries.

What it does:

MAXIDEX contains the steroid dexamethasone, which helps to reduce inflammation.

When it should not be used:**Do not use MAXIDEX if you:**

- Are allergic (*hypersensitive*) to dexamethasone or any of the other ingredients in MAXIDEX (see What the nonmedicinal ingredients are).
- Have herpes simplex keratitis (inflamed cornea of the eye caused by herpes simplex), smallpox, chickenpox or any other viral infection of the eye.
- Have a fungal infection of the eye or an untreated parasitic eye infection.
- Have a mycobacterial infection of the eye, including tuberculosis.
- Have an untreated bacterial eye infection.

What the medicinal ingredient is:

Dexamethasone, 0.1% w/w

What the nonmedicinal ingredients are:

Lanolin oil, methylparaben, propylparaben, white petrolatum

What dosage forms it comes in:

Eye ointment in 3.5 g tube.

WARNINGS AND PRECAUTIONS

BEFORE you use MAXIDEX, talk to your doctor or pharmacist if you:

- Have diabetes. You may be at a higher risk of developing high pressure in the eyes (*intraocular pressure*) or cataracts (*clouding of the lens*).
- Have or have had high pressure in the eye(s), such as glaucoma or ocular hypertension. Your doctor needs to monitor the pressure in your eyes.
- Have a disease that causes thinning of the eye. Small tears (*perforations*) have occurred.
- Are pregnant, might be pregnant or planning to become pregnant.
- Are breastfeeding or planning to breast-feed.

STOP taking MAXIDEX if you develop an eye infection.

While taking MAXIDEX

If you take MAXIDEX for a long time, your doctor should check your eye pressure regularly. This is especially important for children and predisposed individuals, such as those with diabetes. Taking MAXIDEX for an extended time increases the risk of increased eye pressure, glaucoma, vision problems and cataract development.

Taking MAXIDEX for a long time may also put you at risk of developing an eye infection.

You may 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 patients treated with medicines containing ritonavir or cobicistat.

MAXIDEX Ointment contains methylparaben and propylparaben which may cause allergic reactions (possibly delayed).

Pregnancy and Breastfeeding

If you are pregnant or planning to become pregnant, talk to your doctor or pharmacist before using MAXIDEX. If you use large amounts of MAXIDEX and/or for a long time while pregnant, your infant should be observed for signs of hypoadrenalism (*underactive adrenal gland*), such as weakness, fatigue and weight loss.

It is not known if MAXIDEX is present in breastmilk. Talk to your doctor or pharmacist if you are breastfeeding or planning to breast-feed.

Driving and Using Machinery

Your vision may become temporarily blurry after taking MAXIDEX. If this occurs, wait until your vision clears before driving or using machinery.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all the medicines you are taking, recently took or are planning to take, including those obtained without a prescription.

Taking MAXIDEX with nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin and ibuprofen, may slow healing of the eye.

Taking MAXIDEX with ritonavir or cobicistat, may increase the amount of dexamethasone in the blood.

PROPER USE OF THIS MEDICATION

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 applying in your eye(s).

Usual Adult dose:

Apply a ribbon of ointment to the affected eye(s) three to four times a day. As your eye gets better, you may only need to apply a ribbon of ointment coating once a day for several days.

How to use:

1. Tilt your head back.
2. Place a finger on your cheek just under your eye and gently pull down until a “v” pocket is formed between your eyeball and lower eyelid.
3. Apply a ribbon of MAXIDEX ointment in the “v” pocket. Do **not** let the tip of the tube touch your eye, to avoid contaminating the ointment.
4. Look down before closing your eye.
5. Replace the cap of the tube.

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.

Overdose:

If you use more MAXIDEX than you should, rinse it out with lukewarm water. Do not apply more MAXIDEX until it is time for your next regular dose.

No additional side effects are foreseen if you use in the eye more MAXIDEX than you should or if you accidentally ingest the contents of one bottle.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use MAXIDEX, take the missed dose as soon as you remember. 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

A common side effect (seen in 1/10 to 1/100 patients) observed with MAXIDEX is eye discomfort.

Uncommon eye side effects (seen in 1/100 to 1/1000 patients) seen with MAXIDEX include: abnormal or foreign sensation in the eye; eye surface inflammation; dry eye; staining of the eye; sensitivity to light; blurred vision; increased tearing; eyelid crusting; itchy eye; eye irritation; and eye redness.

Uncommon side effects in other parts of the body seen with MAXIDEX include bad taste in the mouth.

Other side effects seen with MAXIDEX include glaucoma, corneal ulcer, increased eye pressure, reduced vision, eye injury, eyelid drooping, eye pain, increased pupil size, dizziness and headache.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Allergic reaction (itching, redness or swelling of the eye)			✓
Uncommon	Cushing's syndrome (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.)		✓	
Frequency Unknown	Infection			✓

This is not a complete list of side effects. For any unexpected effects while taking MAXIDEX, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Prescribing Information, prepared for health professionals can be found at: www.novartis.ca or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last revised: July 13, 2018

MAXIDEX is a registered trademark.

CONSUMER INFORMATION

Pr **MAXIDEX®**
Dexamethasone Ophthalmic Suspension

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What it does:

MAXIDEX contains the steroid dexamethasone, which helps to reduce inflammation.

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- Have herpes simplex keratitis (inflamed cornea of the eye caused by herpes simplex), smallpox, chickenpox or any other viral infection of the eye.
- Have a fungal infection of the eye or an untreated parasitic eye infection.
- Have a mycobacterial infection of the eye, including tuberculosis.
- Have an untreated bacterial eye infection.

What the medicinal ingredient is:

Dexamethasone, 0.1% w/v

What the nonmedicinal ingredients are:

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

What dosage forms it comes in:

Eye drop suspension in 5 mL bottle.

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- Have or have had high pressure in the eye(s), such as glaucoma or ocular hypertension. Your doctor needs to monitor the pressure in your eyes.
- Have a disease that causes thinning of the eye. Small tears (*perforations*) have occurred.
- Are pregnant, might be pregnant or planning to become pregnant.

- Are breastfeeding or planning to breast-feed.

STOP taking MAXIDEX if you develop an eye infection.**While taking MAXIDEX**

If you take MAXIDEX for a long time, your doctor should check your eye pressure regularly. This is especially important for children and predisposed individuals, such as those with diabetes. Taking MAXIDEX for an extended time increases the risk of increased eye pressure, glaucoma, vision problems and cataract development.

Taking MAXIDEX for a long time may also put you at risk of developing an eye infection.

You may 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 patients treated with medicines containing ritonavir or cobicistat.

Contact Lens Wearers

You should not wear contact lenses while using MAXIDEX suspension. MAXIDEX suspension contains the preservative benzalkonium chloride, which is known to affect soft contact lenses. Avoid contact with soft contact lenses. If you must wear contact lenses, remove your contact lenses before applying MAXIDEX suspension and wait at least 15 minutes before putting your lenses back in.

Pregnancy and Breastfeeding

If you are pregnant or planning to become pregnant, talk to your doctor or pharmacist before using MAXIDEX. If you use large amounts of MAXIDEX and/or for a long time while pregnant, your infant should be observed for signs of hypoadrenalism (*underactive adrenal gland*), such as weakness, fatigue and weight loss.

It is not known if MAXIDEX is present in breastmilk. Talk to your doctor or pharmacist if you are breastfeeding or planning to breast-feed.

Driving and Using Machinery

Your vision may become temporarily blurry after taking MAXIDEX. If this occurs, wait until your vision clears before driving or using machinery.

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PROPER USE OF THIS MEDICATION

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

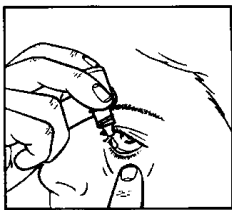
- Only use MAXIDEX for applying in your eye(s).

Usual Adult dose:

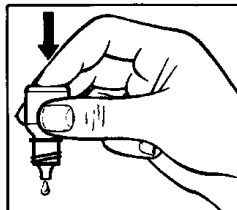
Mild disease: Apply one to two drops in the affected eye(s) 4-6 times daily.

Severe disease: Apply one to two drops in the affected eye(s) every hour. You may reduce the number of drops per day as your eye(s) gets better.

How to use:



1



2

1. Shake MAXIDEX bottle well before use.
2. After cap is removed, if tamper evident snap collar is loose, remove before using product
3. Hold the bottle, pointing down, between your thumb and fingers.
4. Tilt your head back.
5. Pull down your lower eyelid with a clean finger until there is a "v" pocket between your eyelid and your eye. The drop will go in here (picture 1).
6. Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
7. Do not touch your eye, eyelid, surrounding areas or other surfaces with the dropper, to avoid contaminating the suspension.
8. Gently press on the base of the bottle to release one drop at a time. Do not squeeze the bottle. It is designed so that a gentle press on the bottom is all that it needs (picture 2).
9. If you miss, try again.
10. After administration gently close the eyelid and gently press on the tear duct to help the medicine stay in the eye.
11. Close the bottle immediately after use.

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.

Overdose:

If you use more MAXIDEX than you should, rinse it out with lukewarm water. Do not apply more MAXIDEX until it is time for your next regular dose.

No additional side effects are foreseen if you use in the eye more MAXIDEX than you should or if you accidentally ingest the contents of one bottle.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9**

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