PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

PrMAXIDEX®

Dexamethasone Ophthalmic Ointment, USP

Ointment, 0.1% w/w, Ophthalmic

PrMAXIDEX®

Dexamethasone Ophthalmic Suspension, BP

Suspension, 0.1% w/v, Ophthalmic

Sterile

Corticosteroid

Novartis Pharmaceuticals Canada Inc.

700 Saint-Hubert St., Suite 100

Montreal, Quebec H2Y 0C1

www.novartis.ca

Date of Initial Authorization:
April 01, 2001

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RECENT MAJOR LABEL CHANGES

Not applicable.

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

MAXIDEX® (dexamethasone ophthalmic ointment, USP and dexamethasone ophthalmic suspension, BP) is indicated for:

- Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, iritis, cyclitis, and selected infective conjunctivitis when the inherit hazard of steroid use is acceptable to obtain an advisable diminution in edema and inflammation.
- Corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

1.1 Pediatrics

Pediatrics (< 18 years of age): The safety and efficacy of MAXIDEX in children have not been established.

1.2 Geriatrics

Geriatrics (> 60 years of age): No overall differences in safety or effectiveness have been observed between elderly and younger patients.

2 CONTRAINDICATIONS

MAXIDEX is contraindicated in patients with:

- Hypersensitivity to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING .
- Herpes simplex keratitis.
- Vaccinia, varicella and other viral diseases of the cornea and conjunctiva.
- Mycobacterial ocular infections, including tuberculosis of the eye.
- Fungal diseases of ocular structures or untreated parasitic eye infections.
- Acute purulent untreated infections of the eye, which like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid.

4 DOSAGE AND ADMINISTRATION

4.2 Recommended Dose and Dosage Adjustment

MAXIDEX Ointment:

Apply a ribbon of ointment into the conjunctival sac(s) 3-4 times daily. When a favourable response is observed, dosage may be reduced gradually to once a day application for several days.

MAXIDEX Suspension:

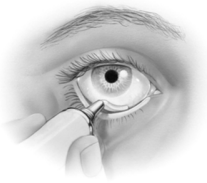
Apply one or two drops into the conjunctival sac(s). In severe diseases, drops may be used hourly, being tapered to discontinuation as the inflammation subsides. In mild disease, drops may be used 4-6 times daily.

4.4 Administration

For ocular use only.

MAXIDEX Ointment:

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. Place a small amount of MAXIDEX in the “v” pocket (picture 1).
4. Look down before closing your eye.
5. Replace the cap of the tube.



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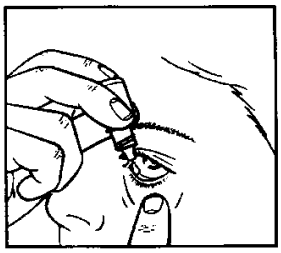
MAXIDEX Suspension:

1. Shake 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 2).
6. Bring the bottle tip close to the eye.
7. 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 3).
8. Nasolacrimal occlusion or gently closing the eyelid after administration is

recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route

9. Close the bottle immediately after use.



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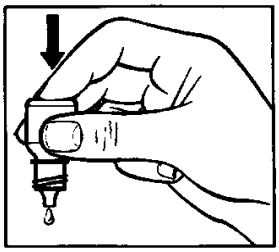

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MAXIDEX Suspension and Ointment:

- Do not let the tip of the tube/dropper touch any surface, as this may contaminate the contents.
- If more than 1 topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Ointments should be administered last.

4.5 Missed Dose

In the case of a missed dose, a patient should take the missed dose as soon as possible. If it is almost time for the next dose, the patient should be instructed to skip the missed dose and continue with their regular dosing schedule. Patients should not use a double dose to make up for the missed dose.

5 OVERDOSAGE

An ocular overdose of MAXIDEX can be flushed from the eye(s) with lukewarm water. Patients should be instructed not to apply any more MAXIDEX until it is time for their next scheduled dose.

Due to the low quantity of medicinal ingredient in a bottle of MAXIDEX, no additional toxic effects are expected with an acute ocular overdose of this product or in the event of accidental ingestion of the contents of one bottle.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1– Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients

Ophthalmic (topical)	Ointment / 0.1% w/w	Anhydrous lanolin oil, methylparaben 0.05% w/w, propylparaben 0.01% w/w and white petrolatum.
Ophthalmic (topical)	Suspension / 0.1% w/v	Benzalkonium chloride 0.01% w/v, citric acid, dibasic sodium phosphate, edetate disodium, hydroxypropyl methylcellulose, polysorbate 80, purified water, sodium chloride, and/or sodium hydroxide (to adjust pH).

Description

MAXIDEX Ointment: MAXIDEX ointment is a sterile ophthalmic ointment, supplied in 3.5 g tubes with ophthalmic tip.

MAXIDEX Suspension: MAXIDEX suspension is a sterile ophthalmic suspension, supplied in 8 mL plastic bottle. Tamper evidence is provided by a closure with an extended skirt that locks to the bottle finish on application and breaks away from the closure on opening.

7 WARNINGS AND PRECAUTIONS

General

For topical use only.

Delayed Wound Healing:

Topical ophthalmic corticosteroids may slow corneal wound healing. Nonsteroidal anti-inflammatory drugs (NSAIDs) are also known to slow or delay healing. Concomitant use of NSAIDs and topical steroids may increase the potential for healing problems.

Driving and Operating Machinery

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

Endocrine and Metabolism

Cushing's syndrome and/or adrenal suppression associated with systemic absorption of ophthalmic dexamethasone may occur after intensive or long-term continuous therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (including ritonavir and cobicistat). (See 9 DRUG INTERACTIONS). In these cases, treatment should not be discontinued abruptly, but progressively tapered.

Immune

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

Prolonged use of corticosteroids may suppress the host immune response and aid in the establishment of ocular bacterial, viral, fungal, or parasitic infections. In acute purulent conditions of the eye, corticosteroids may mask infection or enhance existing infection.

The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid dosing. Corticosteroid therapy should be discontinued if fungal infection occurs.

Ophthalmologic

Prolonged use of topical ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. If MAXIDEX is used for 10 days or longer, intraocular pressure (IOP) should be routinely and frequently monitored. This is especially important in pediatric patients as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults. MAXIDEX is not approved for use in pediatric patients. The risk of corticosteroid-induced raised IOP and/or cataract formation is also increased in predisposed patients (e.g. diabetes).

Corticosteroids should not be used in the presence of glaucoma, ocular hypertension (IOP ≥ 24 mmHg) or a history of steroid-induced IOP elevation unless absolutely necessary and under close ophthalmologic monitoring. Caution should be exercised and duration of treatment with MAXIDEX should be kept as short as possible.

In diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.

The wearing of contact lenses is discouraged during treatment of ocular inflammation. The preservative in MAXIDEX suspension, benzalkonium chloride, may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. However, if the health professional considers contact lense use to be appropriate, patients must be instructed to remove contact lenses prior to application of MAXIDEX suspension and wait at least 15 minutes before re-insertion.

7.1 Special Populations

7.1.1 Pregnant Women

There are no adequate or well-controlled studies evaluating dexamethasone in pregnant women. MAXIDEX should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application. However, no malformations were observed in over 30 pregnancies during which dexamethasone exposure

occurred. Prolonged or repeated corticoid use during pregnancy has been associated with an increased risk of intra-uterine growth retardation. Infants born of mothers who have received prolonged and/or substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

7.1.2 Breast-feeding

It is not known whether dexamethasone is excreted in human breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production or cause other untoward effects. It is not known if ocular administration of corticosteroids could result in sufficient systemic absorption or produce detectable quantities in human milk.

Caution should be exercised when MAXIDEX is administered to nursing women.

7.1.3 Pediatrics

Pediatric patients may be at a higher risk of corticosteroid-induced ocular hypertension (see 7 WARNINGS AND PRECAUTIONS, Ophthalmologic). MAXIDEX is not approved for use in pediatric patients.

7.1.4 Geriatrics

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Ocular adverse reactions generally associated with ophthalmic corticosteroids include glaucoma with optic nerve damage, visual acuity and field defects, cataract formation, secondary ocular infections following suppression of host response, and perforation of the globe.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

A total of 373 patients have been exposed to MAXIDEX suspension or ointment in 6 clinical studies. Adverse reactions reported during clinical trials with MAXIDEX suspension or ointment are classified according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), or very rare (<1/10,000).

Table 2: Adverse Reactions Reported During Clinical Trials with MAXIDEX Suspension or Ointment

System Organ Classification	MedDRA Preferred Term
Nervous system disorders	*Uncommon*: dysgeusia
Eye disorders	*Common:* ocular discomfort *Uncommon*: keratitis, conjuctivitis, dry eye, vital dye staining cornea present, photophobia, vision blurred, eye pruritus, foreign body sensation in eyes, lacrimation increased, abnormal sensation in eye, eyelid margin crusting, eye irritation, ocular hyperaemia

8.5 Post-Market Adverse Reactions

Additional post-marketing adverse reactions include the following:

Endocrine disorders: Cushing's syndrome, adrenal insufficiency;

Eye disorders: glaucoma, ulcerative keratitis, intraocular pressure increased, visual acuity reduced, corneal erosion, eyelid ptosis, eye pain, mydriasis;

Immune system disorders: hypersensitivity;

Nervous system disorders: dizziness, headache.

9 DRUG INTERACTIONS

9.1 Serious Drug Interactions

Concomitant use of topical steroids and NSAIDs may increase the potential for corneal healing problems.

9.4 Drug-Drug Interactions

CYP3A4 inhibitors including ritonavir and cobicistat may increase systemic exposure resulting in increased risk of adrenal suppression/Cushing's syndrome (See 7 WARNING AND PRECAUTIONS, Endocrine and Metabolism). In case this co-administration is required, it should be taken under careful medical supervision.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Dexamethasone is a potent synthetic corticosteroid. It has been demonstrated by animal and human studies based on oral application to possess approximately six to seven times the potency of prednisolone and at least 30 times the potency of cortisone. The potency of this compound is accomplished by the addition of a methyl radical and a fluorine atom to the prednisolone radical.

Dexamethasone suppresses the inflammatory response to a variety of agents, and delays healing.

11 STORAGE, STABILITY AND DISPOSAL

Store at room temperature. Discard the container at the end of treatment and for a maximum period of use after first opening of 4 weeks. Keep out of the reach and sight of children.

12 SPECIAL HANDLING INSTRUCTIONS

Not Applicable.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]MAXIDEX®

Dexamethasone Ophthalmic Ointment

Read this carefully before you start taking **MAXIDEX®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MAXIDEX.**

What is MAXIDEX used for?

- MAXIDEX is used in adults to treat eye inflammation and eye injuries.

How does MAXIDEX work?

MAXIDEX controls inflammatory responses. This helps to reduce inflammation.

What are the ingredients in MAXIDEX?

Medicinal ingredients: Dexamethasone

Non-medicinal ingredients: Lanolin oil, methylparaben, propylparaben, white petrolatum

MAXIDEX comes in the following dosage forms:

Ophthalmic (eye) ointment, 0.1% w/w

Do not use MAXIDEX if you:

- Are allergic to dexamethasone or any of the other ingredients in MAXIDEX or the container
- Have smallpox or chickenpox
- Have any of the following eye problems:
  - herpes simplex keratitis (inflamed cornea of the eye caused by a herpes virus) or any other viral eye infection
  - fungal or an untreated parasitic eye infection
  - mycobacterial infection of the eye, including tuberculosis of the eye
  - untreated bacterial eye infection

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MAXIDEX. Talk about any health conditions or problems you may have, including 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 healthcare professional needs to monitor your eye pressure.
- Have a disease that causes thinning of the eye. MAXIDEX can cause small cuts (perforations) in your eye.

- Are younger than 18 years old.

Other warnings you should know about:

Hormone System and Metabolism:

- MAXIDEX can cause **Cushing's syndrome** (too much corticosteroid getting into your blood).
- MAXIDEX can cause **adrenal insufficiency** (adrenal glands do not make enough adrenal hormones). Suppression of the adrenal gland function may develop after stopping a long-term or intensive MAXIDEX treatment.
- If either happens, your healthcare professional may change your dose or slowly stop treatment with MAXIDEX.

Other Eye Problems and Immune System:

- Taking MAXIDEX for a long time may also put you at risk of these **eye problems**:
    - An eye infection
    - Hiding an eye infection or making an eye infection worse
    - Increased eye pressure, glaucoma, vision problems and cataracts
- Your healthcare professional will check your eye pressure often.
- MAXIDEX eye ointment can slow down eye wound healing.
- MAXIDEX eye ointment contains methylparaben and propylparaben. This may cause **hypersensitivity** (allergic) reactions, which can be delayed.

See the "Serious side effects and what to do about them" table, below, for more information on these and other serious side effects.

Pregnancy and Breastfeeding

- If you are pregnant, planning to get pregnant, or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- Your healthcare professional will monitor your baby if you used large doses or used MAXIDEX for a long time while pregnant. Your baby might get hypoadrenalism (underactive adrenal gland).
- It is not known if MAXIDEX is in breastmilk.
- Talk to your healthcare professional if you are breastfeeding or planning to breast-feed.

Driving and Using Machinery

- MAXIDEX may cause blurry vision for a short time. If this happens, wait until your vision clears before driving or using machinery.

Tell your healthcare professional about all the medicines you are taking, recently took, or will take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

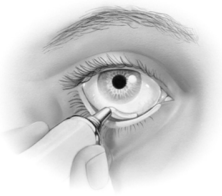
The following may interact with MAXIDEX:

- Nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin and ibuprofen
- Medicines used to treat HIV/AIDS, like ritonavir and cobicistat

How to take MAXIDEX:

- Always use MAXIDEX exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Only use MAXIDEX for applying in your eye(s).
- 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.

MAXIDEX Eye Ointment:



Picture 1

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 (picture 1). 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.

Usual 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 once a day for several days.

Overdose:

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

If you think you, or a person you are caring for, have taken too much MAXIDEX contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of MAXIDEX, take the missed dose as soon as you remember.

- If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take two doses to make up a missed dose.

What are possible side effects from using MAXIDEX?

These are not all the possible side effects you may have when taking MAXIDEX. If you experience any side effects not listed here, tell your healthcare professional.

- bad or altered taste in the mouth
- dizziness, headache

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
UNCOMMON			
Adrenal insufficiency (your adrenal glands do not make enough adrenal hormones): feeling weak and tired, feeling dizzy when you stand up, loss of appetite, nausea, vomiting, diarrhea		✓	
Eye disorders (like corneal ulcer, glaucoma): eye discomfort, feeling something in your eye, more tears, increased pressure in your eyes, eye pain, swelling or redness in or around the eye, changes in vision, hazy or blurred vision, sudden sight loss, dry eyes, increased sensitivity of the eyes to light, itchy eyes, crusty eyelids, pupils larger than normal		✓	
Cushing's syndrome (too much cortisol hormone): swelling weight gain of the body and face, rounded "moon" face, slow healing of cuts, fragile skin that bruises easily, growth of extra body hair (particularly in women), muscle weakness, purple stretch marks on body		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
skin, increased blood pressure, fatigue, bone loss leading to fractures, irregular or missing periods, stunted growth in children			
Hypersensitivity (allergic reaction): itching, redness or swelling of the eye			✓
UNKNOWN			
Infection: redness, itching of the eye, decreased or blurred vision, tearing and increased sensitivity of the eyes to light			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature.
- Discard the container at the end of treatment and for a maximum period of use after first opening of 4 weeks.
- Keep out of reach and sight of children.

If you want more information about MAXIDEX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website http://www.novartis.ca or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised JUL 31, 2023

MAXIDEX is a registered trademark.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMAXIDEX®

Dexamethasone Ophthalmic Suspension

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What is MAXIDEX used for?

- MAXIDEX is used in adults to treat eye inflammation and eye injuries.

How does MAXIDEX work?

MAXIDEX controls inflammatory responses. This helps to reduce inflammation.

What are the ingredients in MAXIDEX?

Medicinal ingredients: Dexamethasone

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

MAXIDEX comes in the following dosage forms:

- Eye drop suspension, 0.1% w/v.

Do not use MAXIDEX if:

- Are allergic to dexamethasone or any of the other ingredients in MAXIDEX or the container.
- Have smallpox or chickenpox
- Have any of the following eye problems:
  - herpes simplex keratitis (inflamed cornea of the eye caused by a herpes virus) or any other viral eye infection
  - fungal or an untreated parasitic eye infection
  - mycobacterial infection of the eye, including tuberculosis of the eye
  - untreated bacterial eye infection

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MAXIDEX. Talk about any health conditions or problems you may have, including 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 healthcare professional needs to monitor your eye pressure.

- Have a disease that causes thinning of the eye. MAXIDEX can cause small cuts (perforations) in your eye.
- Are younger than 18 years old.

Other warnings you should know about:

Hormone System and Metabolism:

- MAXIDEX can cause **Cushing's syndrome** (too much corticosteroid getting into your blood).
- MAXIDEX can cause **adrenal insufficiency** (adrenal glands do not make enough adrenal hormones). Suppression of the adrenal gland function may develop after stopping a long-term or intensive MAXIDEX treatment.
- If either happens, your healthcare professional may change your dose or slowly stop treatment with MAXIDEX.

Other Eye Problems and Immune System:

- Taking MAXIDEX for a long time may also put you at risk of these **eye problems**:
  - An eye infection
  - Hiding an eye infection or making an eye infection worse
  - Increased eye pressure, glaucoma, vision problems and cataracts
- Your healthcare professional will check your eye pressure often.
- MAXIDEX suspension can slow down eye wound healing.

See the "Serious side effects and what to do about them" table, below, for more information on these and other serious side effects.

Pregnancy and Breastfeeding

- If you are pregnant, planning to get pregnant, or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- Your healthcare professional will monitor your baby if you used large doses or used MAXIDEX for a long time while pregnant. Your baby might get hypoadrenalism (underactive adrenal gland).
- It is not known if MAXIDEX is in breastmilk.
- Talk to your healthcare professional if you are breastfeeding or planning to breast-feed.

Driving and Using Machinery

- MAXIDEX may cause blurry vision for a short time. If this happens, wait until your vision clears before driving or using machinery.

Contact Lens Wearers

- You should not wear contact lenses while using MAXIDEX suspension. Avoid contact with soft contact lenses.
- MAXIDEX suspension contains the preservative benzalkonium chloride. This can cause eye irritation and can change the colour of the contact lenses.

- Talk to your healthcare professional if you must wear contact lenses.
  - Remove your contact lenses before applying MAXIDEX suspension. Wait at least 15 minutes before putting your lenses back in.

Tell your healthcare professional about all the medicines you are taking, recently took, or will take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

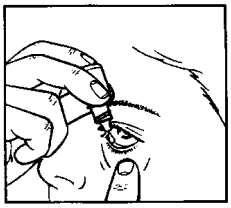
The following may interact with MAXIDEX:

- Nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin and ibuprofen.
- Medicines used to treat HIV/AIDS, like ritonavir and cobicistat.

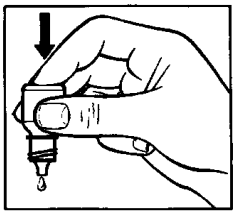
How to take MAXIDEX:

- Always use MAXIDEX exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Only use MAXIDEX for applying in your eye(s).
- 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.

MAXIDEX Eye Suspension:



Picture 1



Picture 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.

Usual dose:

- Mild disease: Apply one to two drops in the affected eye(s), four to six 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.

Overdose:

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

If you think you, or a person you are caring for, have taken too much MAXIDEX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of MAXIDEX, take the missed dose as soon as you remember.
- If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take two doses to make up a missed dose.

What are possible side effects from using MAXIDEX?

These are not all the possible side effects you may have when taking MAXIDEX. If you experience any side effects not listed here, tell your healthcare professional.

- bad or altered taste in the mouth
- dizziness, headache

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
UNCOMMON			
Adrenal insufficiency (your adrenal glands do not make enough adrenal hormones): feeling weak and tired, feeling dizzy when you stand up, loss of appetite, nausea, vomiting, diarrhea		✓	

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Eye disorders (like corneal ulcer, glaucoma): eye discomfort, feeling something in your eye, more tears, increased pressure in your eyes, eye pain, swelling or redness in or around the eye, changes in vision, hazy or blurred vision, sudden sight loss, dry eyes, increased sensitivity of the eyes to light, itchy eyes, crusty eyelids, pupils larger than normal		✓	
Cushing's syndrome (too much cortisol hormone): swelling weight gain of the body and face, rounded "moon" face, slow healing of cuts, fragile skin that bruises easily, growth of extra body hair (particularly in women), muscle weakness, purple stretch marks on body skin, increased blood pressure, fatigue, bone loss leading to fractures, irregular or missing periods, stunted growth in children		✓	
Hypersensitivity (allergic reaction): itching, redness or swelling of the eye			✓
UNKNOWN			
Infection: redness, itching of the eye, decreased or blurred vision, tearing and increased sensitivity of the eyes to light			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad

enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature.
- Discard the container at the end of treatment and for a maximum period of use after first opening of 4 weeks.
- Keep out of reach and sight of children.

If you want more information about MAXIDEX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883].

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