PRESCRIBING INFORMATION

PrMAXIDEX®

Dexamethasone Ophthalmic Ointment, USP

0.1% w/w

PrMAXIDEX®

Dexamethasone Ophthalmic Suspension, USP

0.1% w/v

Sterile

Corticosteroid

Novartis Pharmaceuticals Canada Inc.
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July 13, 2018

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[Pr]MAXIDEX®

Dexamethasone Ophthalmic Ointment
Dexamethasone Ophthalmic Suspension

HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Ophthalmic (topical)	Ointment / 0.1% w/w	Methylparaben and propylparaben. *For a complete listing see Dosage Forms, Composition and Packaging section.*
Ophthalmic (topical)	Suspension / 0.1% w/v	Benzalkonium chloride. *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

MAXIDEX® (dexamethasone ophthalmic ointment and suspension, USP) 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.

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

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 the Dosage Forms, Composition and Packaging section of the Prescribing Information.
- 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.

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 Using 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 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.

Special Populations

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.

Nursing Women: 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.

Pediatrics (< 18 years of age): Pediatric patients may be at a higher risk of corticosteroid-induced ocular hypertension (see WARNINGS AND PRECAUTIONS, Ophthalmologic). MAXIDEX is not approved for use in pediatric patients.

ADVERSE REACTIONS

Adverse Drug 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.

Clinical Trial Adverse Drug Reactions

> *Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.*

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 1: 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

Post-Market Adverse Drug 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.

DRUG INTERACTIONS

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

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

DOSAGE AND ADMINISTRATION

Recommended dose

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.

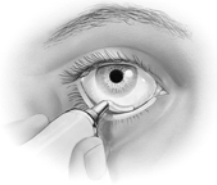
MAXIDEX Suspension:
Apply one or two drops into the conjunctival sac(s). In severe diseases, drops may be used hourly, being tapered to discontinuation as the inflammation subsides. In mild disease, drops may be used 4-6 times daily.

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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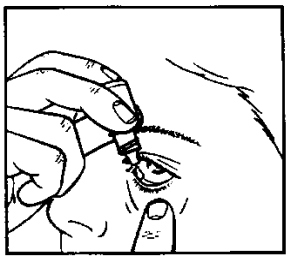
MAXIDEX Suspension:

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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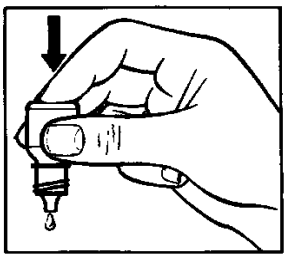

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MAXIDEX Suspension and Ointment:

- 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.

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.

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.

ACTION AND CLINICAL PHARMACOLOGY

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.

STORAGE AND STABILITY

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

DOSAGE FORMS, COMPOSITION AND PACKAGING

MAXIDEX Ointment:
MAXIDEX ointment is a sterile ophthalmic ointment containing the following:
Medicinal ingredient: Dexamethasone 0.1% w/w;
Non-medicinal ingredients: Anhydrous lanolin oil, methylparaben 0.05% w/w, propylparaben 0.01% w/w and white petrolatum.

MAXIDEX ointment is supplied in 3.5 g tubes with ophthalmic tip.

MAXIDEX Suspension:
MAXIDEX suspension is a sterile ophthalmic suspension containing the following:
Medicinal ingredient: Dexamethasone 0.1% w/v;
Non-medicinal ingredients: 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).

MAXIDEX suspension is supplied in 5 mL DROP-TAINER® dispensers. 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.

DROP-TAINER is a registered trademark.

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.

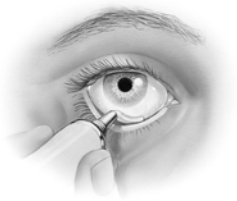
PROPER USE OF THIS MEDICATION

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

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CONSUMER INFORMATION

Pr MAXIDEX®
Dexamethasone Ophthalmic Suspension

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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.

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.

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.

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

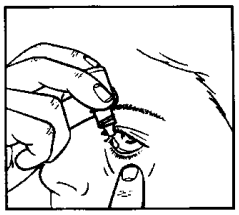
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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

Usual Adult dose:
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:



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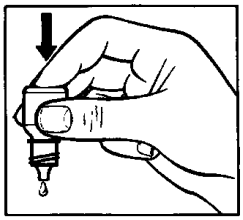

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1. Shake MAXIDEX bottle well before use.
2. After cap is removed, if tamper evident snap collar is loose, remove before using product
3. Hold the bottle, pointing down, between your thumb and fingers.
4. Tilt your head back.
5. Pull down your lower 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.

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.

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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.

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MAXIDEX is a registered trademark.