PRESCRIBING INFORMATION

Pr MAXIDEX*

Dexamethasone Ophthalmic Ointment, USP

0.1% w/w

Pr MAXIDEX*

Dexamethasone Ophthalmic Suspension, USP

0.1% w/v

Sterile

Corticosteroid

Alcon Canada Inc.
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Mississauga, ON L5N 8C7
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September 18, 2015

Submission Control No: 185571

*a trademark of Novartis

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Pr MAXIDEX*

Dexamethasone Ophthalmic Ointment and Suspension

HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Ophthalmic (topical)	Ointment/ 0.1% w/w	None. *For a complete listing see Dosage Forms, Composition and Packaging section.*
Ophthalmic (topical)	Suspension/ 0.1% w/v	Benzalkonium chloride as preservative. *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 conjunctivitides when the inherit hazard of steroid use is acceptable to obtain an advisable diminuition 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 effectiveness of MAXIDEX* have not been established in pediatric patients.

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 most other viral diseases of the cornea and conjunctiva.

- Mycobacterial ocular infections, including tuberculosis of the eye.
- Fungal disease of ocular structures.
- 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.

Infections: Prolonged use of corticosteroids may suppress the host response and aid in the establishment of ocular bacterial, viral or fungal 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.

Delayed Wound Healing: Topical ophthalmic corticosteroids may slow corneal wound healing. Topical nonsteroidal anti-inflammatory drugs (NSAIDs) are also known to slow or delay healing. Concomitant use of topical 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.

Carcinogenesis and Mutagenesis
Long-term animal studies have not been performed to evaluate the carcinogenic potential of MAXIDEX*.

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

Contact lens wear 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. In the event patients are allowed to wear contact lenses, they must be instructed to remove contact lenses prior to application of MAXIDEX* suspension and wait at least 15 minutes before re-insertion.

Sexual Function/Reproduction
Long-term animal studies have not been performed to evaluate the effect of MAXIDEX* on fertility.

Special Populations

Pregnant Women: Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose. In mice, corticosteroids produce fetal resorptions and a specific abnormality, cleft palate. In rabbits, corticosteroids have produced fetal resorptions and multiple abnormalities involving the head, ears, limbs, palate, etc.

There are no adequate or well-controlled studies 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. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

Nursing Women: 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 whether topical administration of corticosteroids could result in sufficient systemic absorption or produce detectable quantities in human milk. Because many drugs are excreted 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 (v.12.1)
Nervous system disorders	*Uncommon*: dysgeusia
Eye disorders	*Common:* ocular discomfort *Uncommon*: abnormal sensation in eye, conjunctivitis, corneal staining, eye irritaton, eyelid margin crusting, eye pruritus, foreign body sensation in eyes, keratitis, keratoconjunctivitis sicca, lacrimation increased, ocular hyperemia, photophobia, vision blurred

Post-Market Adverse Drug Reactions

Additional adverse reactions identified from post-marketing surveillance include the following:
Eye disorders: corneal erosion, eyelid ptosis, eye pain, intraocular pressure increased, mydriasis, visual acuity reduced;
Immune system disorders: hypersensitivity;
Nervous system disorders: dizziness, headache.

DRUG INTERACTIONS

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

DOSAGE AND ADMINISTRATION

MAXIDEX* Ointment:

Apply a small amount 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.

Do not touch dropper tip to any surface, as this may contaminate the contents.

MAXIDEX* Suspension:
SHAKE WELL BEFORE USING.

Apply one or two drops topically in 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.

Do not touch dropper tip to any surface, as this may contaminate the contents.

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.

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 it probably delays or slows 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:
Active: Dexamethasone 0.1% w/w ;
Preservative: Methylparaben 0.05% w/w, propylparaben 0.01% w/w;
Nonmedicinal ingredients: White petrolatum, anhydrous lanolin oil.

MAXIDEX* ointment is supplied in 3.5 gram tubes with ophthalmic tip.

MAXIDEX* Suspension:
MAXIDEX* suspension is a sterile ophthalmic suspension containing the following:
Active: Dexamethasone 0.1% w/v;
Preservative: Benzalkonium chloride 0.01% w/v;
Nonmedicinal ingredients: Purified water, sodium chloride, hydroxypropyl methylcellulose, dibasic sodium phosphate, polysorbate 80, edetate disodium, citric acid 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. After cap is removed: if tamper evidence snap collar is loose, remove before using product.

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 important non-medicinal 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.
- 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 important nonmedicinal ingredients are:
Preservatives: methylparaben, propylparaben
Others: lanolin oil, 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 taking a class of drugs known as nonsteroidal anti-inflammatory drugs (NSAIDs). Taking MAXIDEX* with NSAIDs may slow healing of the eye.
- Are pregnant, might be pregnant or planning to be 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.

Pregnancy and Breastfeeding
If you are pregnant or planning to become pregnant, talk to your doctor or pharmacist before using MAXIDEX*. If you use MAXIDEX* 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 NSAIDs may slow healing of the eye.

PROPER USE OF THIS MEDICATION

Adult dose:
Apply a thin coating to the affected eye(s) three to four times a day. As your eye gets better, you may only need to apply a thin 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. Place a small amount of MAXIDEX* 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.

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.

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.

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 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)**			✓
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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- **Online at MedEffect;**
- **By calling 1-866-234-2345 (toll-free);**
- **By completing a Consumer Side Effect Reporting Form and sending it by:**

- Fax to 1-866-678-6789 (toll-free), or

- Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

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.

MORE INFORMATION

This document plus the full Prescribing Information, prepared for health professionals can be found at:
http://www.alcon.ca
or by contacting the sponsor, Alcon Canada Inc., at:
1-800-613-2245

This leaflet was prepared by Alcon Canada Inc.

Last revised: August 20, 2015

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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.
- 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 important nonmedicinal ingredients are:
Preservative: benzalkonium chloride
Others: citric acid and/or sodium hydroxide (to adjust pH), dibasic sodium phosphate, edetate disodium, hydroxypropyl methylcellulose, polysorbate 80, sodium chloride and purified water.

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 taking a class of drugs known as nonsteroidal anti-inflammatory drugs (NSAIDs). Taking MAXIDEX* with NSAIDs may slow healing of the eye.
- Are pregnant, might be pregnant or planning to be 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.

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 MAXIDEX* 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 NSAIDs may slow healing of the eye.

PROPER USE OF THIS MEDICATION

SHAKE WELL BEFORE USE. After removing the cap: if the security snap collar is loose, remove the snap collar before using MAXIDEX* suspension.

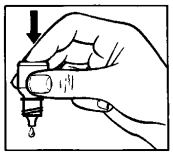
Adult dose:
Mild disease: Apply one to two drops in the affected eye(s) 4-6

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. Get the MAXIDEX* suspension bottle and a mirror.
2. Shake well before use.
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. Close the bottle immediately after use.

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.

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.

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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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 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)			✓
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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

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- **By calling 1-866-234-2345 (toll-free);**
- **By completing a Consumer Side Effect Reporting Form and sending it by:**

- **Fax to 1-866-678-6789 (toll-free), or**
- **Mail to: Canada Vigilance Program**
  Health Canada, Postal Locator 0701E
  Ottawa, ON
  K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

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.

MORE INFORMATION

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