PRESCRIBING INFORMATION

Pr MAXITROL*

Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment, USP
3.5 mg (as neomycin sulfate), 6000 IU/g, 0.1% w/w

Pr MAXITROL*

Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension, USP
3.5 mg (as neomycin sulfate), 6000 IU/mL, 0.1% w/v

STERILE

Anti-inflammatory/Antibiotic

Alcon Canada Inc.
2665 Meadowpine Blvd
Mississauga, ON Canada
L5N 8C7
www.alcon.ca

Date of Preparation:
June 29, 2015

Submission Control No: 182791

*a trademark of Novartis

Table of Contents

PART I: HEALTH PROFESSIONAL INFORMATION....3
SUMMARY PRODUCT INFORMATION....3
INDICATIONS AND CLINICAL USE....3
CONTRAINDICATIONS....4
WARNINGS AND PRECAUTIONS....4
ADVERSE REACTIONS....6
DRUG INTERACTIONS....6
DOSAGE AND ADMINISTRATION....6
OVERDOSAGE....6
STORAGE AND STABILITY....7
DOSAGE FORMS, COMPOSITION AND PACKAGING....7

PART III: CONSUMER INFORMATION....8

PART III: CONSUMER INFORMATION....11

PRESCRIBING INFORMATION

[Pr] MAXITROL*

Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment, USP
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension, USP

HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Ophthalmic (topical)	Ointment/ dexamethasone 0.1% w/w, neomycin 3.5 mg/g (as neomycin sulfate), polymyxin B sulfate 6000 IU/g	None. *For a complete listing see Dosage Forms, Composition and Packaging section.*
Ophthalmic (topical)	Suspension/ dexamethasone 0.1% w/v, neomycin 3.5 mg/mL (as neomycin sulfate), polymyxin B sulfate 6000 IU/mL	Benzalkonium chloride as preservative. *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

MAXITROL* (neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment and suspension) is indicated in the management of infectious ocular inflammations produced by organisms, which are sensitive to neomycin sulfate and polymyxin B sulfate:

- Acute or chronic, non-purulent conjunctivitis, blepharoconjunctivitis, keratoconjunctivitis
- Non-specific superficial keratoconjunctivitis, and acne rosacea keratitis
- Iridocyclitis
- Mild acute iritis
- Recurrent marginal ulceration[†]
- Corneal ulcer[†]
- Blepharitis, non-purulent
- Scleritis, episcleritis, and scleroconjunctivitis.
- Postoperative to aid in prevention of ophthalmic case of infections

[†]MAXITROL* should be used with care in diseases causing thinning of the cornea, because of the danger of perforation.

CONTRAINDICATIONS

MAXITROL* is contraindicated in patients with:

- Hypersensitivity to dexamethasone, neomycin sulfate, polymyxin B sulfate or to any other 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
- Fungal diseases of the eye
- Mycobacterial ocular infections, including tuberculosis of the eye

Acute purulent untreated infections of the eye, which, like other diseases caused by micro-organisms, may be masked or enhanced by the presence of the steroid.

WARNINGS AND PRECAUTIONS

General

A few individuals may be sensitive to one or more components of this product. If any reactions indicating sensitivity are observed, discontinue use.

Sensitivity to topically administered aminoglycosides, such as neomycin, may occur in some patients. If hypersensitivity develops during use of MAXITROL*, discontinue use. Additionally, topical use of neomycin may lead to skin sensitization.

Cross-hypersensitivity to other aminoglycosides can occur, and the possibility that patients who become sensitized to topical neomycin may also be sensitive to other topical and/or systemic aminoglycosides should be considered.

Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic neomycin or when applied topically to open wounds or damaged skin. Nephrotoxic and neurotoxic reactions have also occurred with systemic polymyxin B. Although these effects have not been reported following topical ocular use of this product, caution is advised when used concomitantly with systemic aminoglycoside or polymyxin B therapy.

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.

Infections

Corticosteroids may reduce resistance to and aid in the establishment of non-susceptible bacterial, fungal or viral infections and mask the clinical signs of infection.

Fungal infection should be suspected in patients with persistent corneal ulceration. If fungal infection occurs, corticosteroids therapy should be discontinued.

Prolonged use of antibiotics, such as neomycin and polymyxin, may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy.

Ophthalmologic

Extended ophthalmic use of corticosteroid drugs may result in ocular hypertension and/or glaucoma with damage to the optic nerve, reduced visual acuity and visual field defects, and posterior subcapsular cataract formation. In patients receiving prolonged ophthalmic corticosteroid therapy, intraocular pressure should be checked routinely and frequently. 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. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).

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 an ocular inflammation or infection. MAXITROL* suspension contains benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses. Patients should be advised to 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 MAXITROL* suspension and wait at least 15 minutes before reinsertion.

Sexual Function/Reproduction

There are no available data on the use of this medicine affecting male or female fertility.

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 application, the patient should be advised to wait until vision clears before driving or using machinery.

Special Populations

Pregnant Women: Although topical steroids have not been reported to have an adverse effect on pregnancy, the safety of their use in pregnancy has not absolutely been established. Therefore it is advisable not to use this product for long-term treatment on pregnant patients.

Nursing Women: It is unknown whether topical ophthalmic dexamethasone, neomycin or polymyxin B is excreted in human milk. However, since systemic corticosteroids and aminoglycosides may be distributed into milk, a risk to the suckling child cannot be excluded.

Pediatrics: Pediatric patients may be at a higher risk of corticosteroid-induced ocular hypertension (see WARNINGS AND PRECAUTIONS, Ophthalmologic).

ADVERSE REACTIONS

The following uncommon (≥1/1 000 to <1/100) adverse reactions have been observed with MAXITROL* ointment and suspension:

Immune system disorders: hypersensitivity
Eye disorders: keratitis, intraocular pressure increased, vision blurred, photophobia, mydriasis, eyelid ptosis, eye pain, eye swelling, eye pruritus, ocular discomfort, foreign body sensation in eyes, eye irritation, ocular hyperaemia and lacrimation increased

DRUG INTERACTIONS

No drug interaction studies have been performed with MAXITROL*.

Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems (see WARNINGS AND PRECAUTIONS, General).

No drug-food, drug-herb, drug-laboratory interactions or drug-lifestyle interactions are known.

DOSAGE AND ADMINISTRATION

MAXITROL* Ointment
Apply a thin coating to the conjunctival sacs of the affected eye(s) topically three to four times daily. Frequency of application may be reduced gradually to once a day application for several days after 3 to 4 days when a satisfactory response has been obtained.

MAXITROL* Suspension
SHAKE WELL BEFORE USE. Instill one to two drops topically in the conjunctival sac of the affected eye(s) four to six times daily. Dosage may be reduced after 3 to 4 days when a satisfactory response has been obtained.

OVERDOSAGE

No toxic effects are expected when MAXITROL* ointment or suspension are administered to the eye at either the recommended dose or in the event of accidental ingestion of the contents of a tube/bottle.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

STORAGE AND STABILITY

Do not store above 25°C. Do not refrigerate. Keep out of reach and sight of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

MAXITROL* Ointment

MAXITROL* ointment is a sterile topical ophthalmic ointment containing the following:

Medicinal ingredients: Dexamethasone 0.1% w/w, Neomycin 3.5 mg/g (as Neomycin Sulfate) and Polymyxin B Sulfate 6000 IU/g.
Preservatives: Methylparaben 0.05% w/w, Propylparaben 0.01% w/w.
Non-medicinal Ingredients: White Petrolatum and Anhydrous Liquid Lanolin.

MAXITROL* ointment is supplied in 3.5 g tube dispensers with ophthalmic tip.

MAXITROL* Suspension

MAXITROL* suspension is a sterile topical ophthalmic suspension containing the following:

Medicinal ingredients: Dexamethasone 0.1% w/v, Neomycin 3.5 mg/mL (as Neomycin Sulfate) and Polymyxin B Sulfate 6000 IU/mL.
Preservative: Benzalkonium Chloride 0.004% w/v.
Non-medicinal Ingredients: Purified Water, Sodium Chloride, Hydroxypropyl Methylcellulose, Polysorbate 20, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH).

MAXITROL* suspension is supplied in 5 mL sterile 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 evident snap collar is loose, remove before using product.

CONSUMER INFORMATION

MAXITROL*
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment, USP

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MAXITROL* ointment. Contact your doctor or pharmacist if you have any questions about MAXITROL* ointment.

ABOUT THIS MEDICATION

What the medication is used for:
MAXITROL* ointment is used to treat inflammation of the eye caused by microorganisms.

What it does:
MAXITROL* ointment contains a steroid, dexamethasone, and two antibiotics, neomycin sulfate and polymyxin B sulfate. The antibiotics, neomycin and polymyxin B sulfates, work by reducing infection while dexamethasone helps to reduce inflammation.

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

- Are allergic to dexamethasone, neomycin sulfate, polymyxin B sulfate or any of the other ingredients in MAXITROL* ointment (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.

What the medicinal ingredient is:

- Dexamethasone, 0.1% w/w
- Neomycin 3.5 mg/g (as neomycin sulfate)
- Polymyxin B sulfate, 6000 IU/g

What the important nonmedicinal ingredients are:

- **Preservatives:** methylparaben, propylparaben
- **Others:** liquid lanolin, white petrolatum

What dosage forms it comes in:
Eye ointment in 3.5 tubes

WARNINGS AND PRECAUTIONS

BEFORE you use MAXITROL* ointment, talk to your doctor or pharmacist if you:

- Have a disease that causes thinning of the eye. Small tears (perforations) have occurred.
- Are taking other antibiotics.
- Are taking a class of drugs known as Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). Taking MAXITROL* ointment with NSAIDs may slow healing of the eye.
- Are pregnant, might be pregnant or may become pregnant.
- Are breastfeeding or planning to breast-feed.

STOP taking MAXITROL* ointment if you:

- Develop any signs of an allergic reaction, such as itching, swelling or redness of the eyes or skin redness, irritation or discomfort.
- Develop an infection.

While taking MAXITROL* ointment
If you take MAXITROL* ointment for a long time, your doctor should check your eye pressure regularly. This is especially important for children and in predisposed individuals, such as those with diabetes. Taking MAXITROL* ointment for an extended time increases the risk of increased eye pressure, glaucoma, vision problems and developing cataracts.

Taking MAXITROL* ointment for a long time also may put you at risk for developing an infection.

Pregnancy and Breastfeeding
There have been no reported problems with using topical steroids, such as dexamethasone, while pregnant. However, MAXITROL* ointment should not be used in the long-term treatment of pregnant women.

It is not known if MAXITROL* ointment is present in breast milk. Talk to your doctor or pharmacist if you are breast-feeding.

Driving and Using Machinery
Your vision may become temporarily blurry after taking MAXITROL* ointment. If this occurs, wait until your vision clears before driving or using machinery.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or plan to take any other medicines, including those obtained without a prescription.

Taking MAXITROL* ointment with other antibiotics may increase the seriousness of an allergic reaction and other side effects.

Taking MAXITROL* ointment with NSAIDs may slow healing of the eye.

PROPER USE OF THIS MEDICATION

Usual adult dose:
Apply a thin coating to the affected eye(s) three to four times a day. After 3 to 4 days, you may reduce gradually to applying a thin coating only one a day.

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 MAXITROL* 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.

Overdose:

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, MAXITROL* ointment can cause side effects, although not everybody gets them.

Uncommon side effects (affects 1 to 10 people in 1000) that can occur with MAXITROL* ointment include:

- eye surface inflammation
- increased eye pressure
- blurry vision
- sensitivity to light
- pupil dilation
- drooping eyelid
- eye pain, swelling or redness
- itchy eyes
- eye discomfort
- abnormal feeling in the eye
- tearing

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 MAXITROL* ointment, contact your doctor or pharmacist.

HOW TO STORE IT

Do not store above 25°C. Do not refrigerate. 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 0701D
    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 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: April 13, 2015

CONSUMER INFORMATION

MAXITROL*
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension, USP

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MAXITROL* suspension. Contact your doctor or pharmacist if you have any questions about MAXITROL* suspension.

ABOUT THIS MEDICATION

What the medication is used for:
MAXITROL* suspension is used to treat inflammation of the eye caused by microorganisms.

What it does:
MAXITROL* suspension contains a steroid, dexamethasone, and two antibiotics, neomycin sulfate and polymyxin B sulfate. The antibiotics, neomycin and polymyxin B sulfates, work by reducing infection while dexamethasone helps to reduce inflammation.

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

- Are allergic to dexamethasone, neomycin sulfate, polymyxin B sulfate or any of the other ingredients in MAXITROL* suspension (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.

What the medicinal ingredient is:

- Dexamethasone, 0.1% w/v
- Neomycin 3.5 mg/mL (as neomycin sulfate)
- Polymyxin B sulfate, 6000 IU/mL

What the important nonmedicinal ingredients are:

- **Preservative:** benzalkonium chloride
- **Other:** hydroxypropylmethylcellulose, polysorbate 80, sodium chloride, hydrochloric acid/and or sodium hydroxide (to adjust pH) and purified water

What dosage forms it comes in:
Suspension in 5mL DROP-TAINER* dispenser

WARNINGS AND PRECAUTIONS

BEFORE you use MAXITROL* suspension talk to your doctor or pharmacist if you:

- Have a disease that causes thinning of the eye. Small tears (perforations) have occurred.
- Are taking other antibiotics.
- Are taking a class of drugs known as Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). Taking MAXITROL* suspension with NSAIDs may slow healing of the eye.
- Wear contacts.
- Are pregnant, might be pregnant or may become pregnant.
- Are breastfeeding or planning to breast-feed.

STOP taking MAXITROL* suspension if you:

- Develop any signs of an allergic reaction, such as itching, swelling or redness of the eyes or skin redness, irritation or discomfort.
- Develop an infection.

While taking MAXITROL* suspension
If you are take MAXITROL* suspension for a long time, your doctor should check your eye pressure regularly. This is especially important for children and in predisposed individuals, such as those with diabetes. Taking MAXITROL* suspension for an extended time increases the risk of increased eye pressure, glaucoma, vision problems and developing cataracts.

Taking MAXITROL* suspension for a long period of time may also put you at risk for developing an infection.

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

Pregnancy and Breastfeeding
There have been no reported problems with using topical steroids, such as dexamethasone, while pregnant. However, MAXITROL* suspension should not be used in the long-term treatment of pregnant women.

It is not known if MAXITROL* suspension is present in breast milk. Talk to your doctor or pharmacist if you are breast-feeding.

Driving and Using Machinery
Your vision may become temporarily blurry after taking MAXITROL* suspension. If this occurs, wait until your vision clears before driving or using machinery.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or plan to take any other medicines, including those obtained without a prescription.

Taking MAXITROL* suspension with other antibiotics may increase the seriousness of an allergic reaction and other side effects.

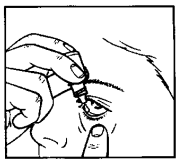
Taking MAXITROL* suspension with NSAIDs may slow healing of the eye.

PROPER USE OF THIS MEDICATION

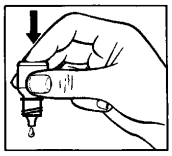
SHAKE WELL BEFORE USE. After removing the cap, if the tamper evident snap collar is loose, remove the snap collar before using MAXITROL* suspension

Usual adult dose:
Apply one to two drops in the affected eye(s) 4-6 times daily. You may reduce the number of drops after 3 to 4 days as directed by your doctor or pharmacist.

How to use:



1



2

1. Get the MAXITROL* 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:

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, MAXITROL* suspension can cause side effects, although not everybody gets them.

Uncommon side effects (affects 1 to 10 people in 1000) that can occur with MAXITROL* suspension include:

- eye surface inflammation
- increased eye pressure
- blurry vision
- sensitivity to light
- pupil dilation
- drooping eyelid
- eye pain, swelling or redness
- itchy eyes
- eye discomfort
- abnormal feeling in the eye
- tearing

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 MAXITROL* suspension, contact your doctor or pharmacist.

HOW TO STORE IT

Do not store above 25°C. Do not refrigerate. 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 0701D
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 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: June 29, 2015