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

Novartis Pharmaceuticals Canada Inc.
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Date of Revision:
August 8, 2018

Submission Control No: 214822

Novartis version:
March 01, 2024

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Pr **MAXITROL®**

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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	Methylparaben and propylparaben as preservatives and lanolin *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 contains antibacterial ingredients, neomycin and polymyxin B. To reduce the development of drug-resistant bacteria and maintain the effectiveness of neomycin and

polymyxin B, MAXITROL should only be used for the authorized indication and clinical use.

†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 or untreated parasitic eye infections.
- 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.

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

MAXITROL ointment contains lanolin, which may cause local skin reactions (e.g. contact dermatitis).

Sensitivity to topically administered aminoglycosides, such as neomycin, may occur in some patients. Severity of hypersensitivity reactions may vary from local effects to generalized reactions such as erythema, itching, urticarial, skin rash, anaphylaxis, anaphylactoid reactions, or bullous reactions. 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.

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.

Infections

Corticosteroids may reduce resistance to and aid in the establishment of non-susceptible bacterial, fungal, parasitic 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.

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.

Susceptibility/Resistance

Development of Drug Resistant Bacteria: Prescribing MAXITROL in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth

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.

Sexual Function/Reproduction

There are no available data on the use of neomycin or polymyxin B affecting male or female fertility. There is limited clinical data to evaluate the effect of dexamethasone on 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. There are no or limited amount of data from the use of dexamethasone, neomycin or polymyxin B in pregnant women. Aminoglycoside antibiotics, such as neomycin, do cross the placenta after intravenous dosing in pregnant women. Non-clinical and clinical systemic exposure to aminoglycosides has been shown to induce ototoxicity and nephrotoxicity. 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 substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism. MAXITROL is not recommended during pregnancy.

Nursing Women: It is unknown whether topical ophthalmic dexamethasone, neomycin or polymyxin B are excreted in human milk. Aminoglycosides and corticosteroids are excreted in human milk after systemic administration. No data is available on the passage of dexamethasone and polymyxin B into human breast milk. A risk to the breastfed child cannot be excluded. MAXITROL is not recommended while breastfeeding, unless the benefits to the nursing woman and child outweigh the risks.

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 in clinical studies:

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

Post-Market Adverse Drug Reactions

Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data.

Eye disorders: ulcerative keratitis
Nervous system disorders: headache
Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome

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).

CYP3A4 inhibitors including ritonavir and cobicistat may increase systemic exposure resulting in increased risk of adrenal suppression/Cushing's syndrome. (see WARNINGS AND PRECAUTIONS, Endocrine and Metabolism). The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side effects, in which case patients should be monitored for systemic corticosteroid effects.

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.

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 and result in a decrease in systemic adverse reactions.

Missed dose
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.

OVERDOSAGE

Due to the characteristics of this preparation, no additional toxic effects are expected with an acute ocular overdose of MAXITROL ointment or suspension, nor 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 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

Pr 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.

MAXITROL ointment contains antibacterial drugs. Antibacterial drugs treat only bacterial infections. They do not treat viral infections.

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 or an untreated parasitic eye infection.
- Have a mycobacterial infection of the eye, including tuberculosis.

What the medicinal ingredients are:

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

What the important non-medicinal ingredients are:

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

What dosage forms it comes in:
Eye ointment in 3.5 g tube.

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.
- Wear contacts.
- Have had a reaction to neomycin or other aminoglycoside antibiotics in the past.

STOP taking MAXITROL ointment if you:

- Develop any signs of an allergic reaction, such as itching, redness, swelling of the eyes, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, stomach cramps, blistering skin rash, fever, muscle or joint pain.
- Develop an infection.

While taking MAXITROL ointment:
Use of this medicine may cause skin redness, irritation and discomfort.

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.

Corticosteroid side effects (such as swelling around the trunk and in the face area with weight gain) may occur when corticosteroids become absorbed into your blood. This may occur after intensive or long-term continuous treatment with an ophthalmic corticosteroid such as dexamethasone contained in MAXITROL ointment. Predisposed patients, including children and patients treated with medicines containing ritonavir or cobicistat (used to treat HIV/AIDS), are especially at risk. Talk to you doctor if you experience swelling around the trunk and in the face area with weight gain. Do not stop using MAXITROL ointment suddenly without first talking to your doctor.

MAXITROL ointment contains methylparaben and propylparaben which may cause allergic reactions.

MAXITROL ointment contains lanolin, which may cause local skin reactions.

Pregnancy and Breastfeeding
If you are pregnant or breast-feeding, you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. MAXITROL ointment is not recommended during pregnancy or breastfeeding.

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.

Taking MAXITROL ointment with ritonavir or cobicistat, used to treat HIV/AIDS, may increase the amount of dexamethasone in the blood.

PROPER USE OF THIS MEDICATION

Although you may feel better early in treatment, MAXITROL ointment should be used exactly as directed.

Misuse or overuse of MAXITROL ointment could lead to the growth of bacteria that will not be killed by MAXITROL ointment (resistance). This means that MAXITROL ointment may not work for you in the future.

Do not share your medicine.

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.

If you are using other eye drop or eye ointment medicines, wait at least 5 minutes between each medicine. Eye ointments should be administered last.

Overdose:
If you use more MAXITROL ointment than you should, rinse it all out with warm water. Do not put in any more ointment 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.

Missed Dose:
If you forget to use MAXITROL ointment, continue with the next dose as planned. 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, MAXITROL ointment can cause side effects, although not everybody gets them.

Side effects may 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
- eye irritation
- abnormal feeling in the eye
- tearing
- 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 seek immediate medical help
		Only if severe	In all cases	
Uncommon	**Allergic Reaction:** itching, redness or swelling of the eye, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Unknown	**New Infection:** eye swelling, weeping, drainage, crusting			✓
	Corneal Ulcer: eye redness, pain, tearing, sensitivity to light, vision problems		✓	
	Skin Reactions: skin rash, which may blister, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge), widespread rash with blisters and skin peeling on much of the body, particularly around the mouth, nose, eyes and genitals			✓

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 25ºC. Do not refrigerate. Keep out of the reach and sight of children.

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/adverse-reaction-reporting.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.

MORE INFORMATION

This document plus the 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.

MAXITROL is a registered trademark.

Last revised: August 8, 2018

Novartis Version: March 30, 2023

CONSUMER INFORMATION

PrMAXITROL®
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.

MAXITROL suspension contains antibacterial drugs. Antibacterial drugs treat only bacterial infections. They do not treat viral infections.

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 or an untreated parasitic eye infection.
- Have a mycobacterial infection of the eye, including tuberculosis.

What the medicinal ingredients are:
- Dexamethasone, 0.1% w/v
- Neomycin 3.5 mg/mL (as neomycin sulfate)
- Polymyxin B sulfate, 6000 IU/mL

What the important non-medicinal ingredients are:
- **Preservative:** benzalkonium chloride
- **Others:** hydroxypropylmethylcellulose, polysorbate 20, sodium chloride, hydrochloric acid/and or sodium hydroxide (to adjust pH) and purified water.

What dosage forms it comes in:
Suspension in 5mL 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.
- Have had a reaction to neomycin or other aminoglycoside antibiotics in the past.

STOP taking MAXITROL suspension if you:
- Develop any signs of an allergic reaction, such as itching, redness, swelling of the eyes, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, stomach cramps, blistering skin rash, fever, muscle or joint pain.
- Develop an infection.

While taking MAXITROL suspension:
Use of this medicine may cause skin redness, irritation and discomfort.

If you 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.

Corticosteroid side effects (such as swelling around the trunk and in the face area with weight gain) may occur when corticosteroids become absorbed into your blood. This may occur after intensive or long-term continuous treatment with an ophthalmic corticosteroid such as dexamethasone contained in MAXITROL suspension. Predisposed patients, including children and patients treated with medicines containing ritonavir or cobicistat (used to treat HIV/AIDS), are especially at risk. Talk to you doctor if you experience swelling around the trunk and in the face area with weight gain. Do not stop using MAXITROL suspension suddenly without first talking to your doctor.

You should not wear contact lenses while using MAXITROL suspension. MAXITROL suspension contains the preservative benzalkonium chloride, which may cause eye irritation and is also 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
If you are pregnant or breast-feeding, you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. MAXITROL suspension is not recommended during pregnancy or breastfeeding.

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.

Taking MAXITROL suspension with ritonavir or cobicistat, used to treat HIV/AIDS, may increase the amount of dexamethasone in the blood.

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.

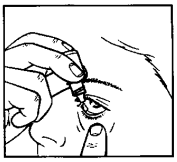
Although you may feel better early in treatment, MAXITROL suspension should be used exactly as directed.

Misuse or overuse of MAXITROL suspension could lead to the growth of bacteria that will not be killed by MAXITROL suspension (resistance). This means that MAXITROL suspension may not work for you in the future.

Do not share your medicine.

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:



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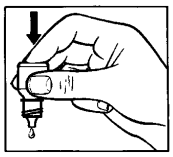

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1. Get the MAXITROL suspension bottle and a mirror.
2. Shake well before use.
3. Hold the bottle, pointing down, between your thumb and fingers.
4. Tilt your head back.
5. Pull down your lower eyelid with a clean finger until there is a "v" pocket 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. Keep the eyelid closed, while simultaneously applying gentle pressure to the tear duct with a finger to limit the amount of medicine that will come into the blood after application of the eye drops.
10. If a drop misses your eye, try again.
11. Close the bottle immediately after use.

If you are using other eye drop or eye ointment medicines, wait at least 5 minutes between each medicine. Eye ointments should be administered last.

Overdose:
If you use more MAXITROL suspension than you should, rinse it all out with warm water. Do not put in any more suspension 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.

Missed Dose:
If you forget to use MAXITROL suspension, continue with the next dose as planned. 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, MAXITROL suspension can cause side effects, although not everybody gets them.

Side effects may 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
- eye irritation
- abnormal feeling in the eye
- tearing
- 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 seek immediate medical help
		Only if severe	In all cases	
Uncommon	**Allergic Reaction:** itching, redness or swelling of the eye, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Unknown	**New Infection:** swelling, weeping, drainage, crusting			✓
	Corneal Ulcer: eye redness, pain, tearing, sensitivity to light, vision problems		✓	
	Skin Reactions: skin rash, which may blister, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge), widespread rash with blisters and skin peeling on much of the body, particularly around the mouth, nose, eyes and genitals			✓

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 25ºC. Do not refrigerate. Keep out of the reach and sight of children.

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/adverse-reaction-reporting.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.

MORE INFORMATION

This document plus the 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.

MAXITROL is a registered trademark.

Last revised: August 8, 2018

Novartis Version: March 01, 2024