

CONSUMER INFORMATIONPr **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 your 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.

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

HOW TO STORE IT

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

CONSUMER INFORMATION

Pr 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.

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 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.
- 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.

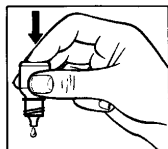
Usual adult dose:

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:



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

4. fingers.
5. Tilt your head back.
6. 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).
7. Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
8. Do not touch your eye, eyelid, surrounding areas or other surfaces with the dropper, to avoid contaminating the suspension.
9. 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).
10. 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.
11. If a drop misses your eye, try again.
12. 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.

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