

MAXITROL OINTMENT

Consumer Medication Information Leaflet (RiMUP)

Dexamethasone / Neomycin Sulfate / Polymyxin B Sulfate (1mg / 3,500 IU / 6000 IU)

What is in this leaflet

1. What Maxitrol Ointment is used for
2. How Maxitrol Ointment works
3. Before you use Maxitrol Ointment
4. How to use Maxitrol Ointment
5. While you are using it
6. Side effects
7. Storage and Disposal of Maxitrol Ointment
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Maxitrol Ointment is used for

Maxitrol is indicated for eye inflammation and bacterial infections in the external part of the eye.

How Maxitrol Ointment works

Maxitrol combines two antibiotics, neomycin sulfate and polymyxin B sulfate, offering broad spectrum antibacterial activity with the anti-inflammatory activity of a corticosteroid, dexamethasone, for combating certain microbial infections.

Before you use Maxitrol Ointment

- When you must not use it

Do not use Maxitrol Ointment

- If you are allergic to dexamethasone, neomycin, polymyxin B or any of the other ingredients of Maxitrol Ointment.
- If you think you have viral, fungal or bacterial infection in the eye.

Safety and effectiveness of MAXITROL in children have not been established.

Pregnancy and breast-feeding

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 breast-feeding.

- Before you start to use it

- If you experience allergic reactions with Maxitrol Ointment, discontinue use and consult your doctor. Allergic reactions may vary from localized itching or skin redness to severe allergic reactions (anaphylactic reaction) or serious skin reactions. These allergic reactions may occur with other antibiotics of the same family (aminoglycosides).
- If you use Maxitrol Ointment for a long period of time, you may:
 - Have increased pressure in your eye(s). You should have your eye pressure checked regularly while using Maxitrol Ointment especially if you have diabetes.
 - Develop cataract
 - Become more susceptible to eye infections
 - Develop Cushing's syndrome due to the medicine getting into your blood. Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of the syndrome.
- If your symptoms get worse or suddenly return, please consult your doctor. You may become more susceptible to eye infections with the use of this product.
- Consult your doctor or pharmacist if you have diabetes or disorder causing thinning of the eye tissues before using this medicine.
- If you wear contact lenses:
 - Wearing contact lenses (hard or soft) is not recommended during treatment of an eye inflammation or infection.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Especially tell your doctor if you are using:

- Topical NSAIDs or steroids (used to treat skin inflammation)
- Ritonavir or cobicistat (used to treat HIV).

How to use Maxitrol Ointment

- How much to use

Adults and Elderly

Apply a small amount into the eye(s).

- When to use it

Use up to 3 or 4 times daily or, may be used adjunctively with drops at bedtime or use as directed by your doctor or pharmacist.

- How long to use it

Continue using Maxitrol Ointment for as long as your doctor recommends.

- If you forget to use it

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.

- If you use too much (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.

While you are using it

- Things you must do

- Always use this medicine exactly as your doctor or pharmacist or nurse has told you.
- Check with your doctor or pharmacist or nurse if you are not sure.
- Only use Maxitrol Ointment in your eyes.

- Things you must not do

Do not let the tip of the tube touch your eye.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Maxitrol Ointment to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- This product contains methylparahydroxybenzoate and propylparahydroxybenzoate which may cause allergic reactions.
- This product contains wool fat which may cause local skin inflammation.
- 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.
- Check with the doctor if you have persistent corneal ulcer.

Driving and using machines

Ointments in particular can cause blurry vision and should not be used prior to when you expect to drive or operate machinery.

Side effects

Like all medicines, Maxitrol Ointment can cause side effects, although not everybody gets them. The following side effects have been seen with Maxitrol Ointment:

- Uncommon side effects (may occur in 1 to 10 users in 1,000):
 - Effects in the eye: eye surface inflammation, increased eye pressure, itchy eye, eye discomfort, eye irritation

Additional side effects from post-marketing experience that have been reported for which the frequency is not known:

- Effects in the eye: corneal ulcer, blurred vision, sensitivity to light, increase in pupil size, drooping of eyelid, eye pain, eye swelling, abnormal sensation in the eye, eye redness, increased tear production
- General side effects: allergy, headache, serious skin reactions (Stevens-Johnson syndrome).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Serious adverse reactions including toxicity to the nerve, ear and kidney have occurred in people taking neomycin or when applied topically to open wounds or damaged skin. Toxicity to the nerve and kidney have also occurred with polymyxin B. Although these effects have not been reported following this eye product, caution is advised when used concomitantly with other similar antibiotics.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Maxitrol Ointment

- Storage

Do not store above 25°C.
Discard one month after opening.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These

measures will help to protect the environment.

Product Description

- What it looks like

Sterile eye ointment
A greasy, translucent to opaque and white to light yellow, homogeneous ointment, free of lumps.

- Ingredients

- Active ingredients
1 mg dexamethasone, 3,500 (International Units) IU of neomycin sulfate and 6,000 IU polymyxin B sulfate.

- Inactive ingredients
Methyl p-hydroxybenzoate (E218), Propyl p-hydroxybenzoate (E216), wool fat and white petrolatum.

- MAL number:

MAL19910106ARZ

Manufacturer

S.A. Alcon Couvreur N.V.
Rijksweg 14,
2870 Puurs, Belgium.

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.
Level 18, Imazium,
No. 8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor

Current PI version

TDOC-0051679 Version: 2.0

Date of revision

25/01/2022

Serial Number

NPRA (R1/1) 14012022/020