

MAXITROL SUSPENSION EYE DROP

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

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What Maxitrol Suspension is used for

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

How Maxitrol Suspension 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 Suspension

When you must not use it

Do not use Maxitrol Suspension

- If you are allergic to dexamethasone, neomycin, polymyxin B or any of the other ingredients of Maxitrol Suspension.
- If you think you have:
 - Herpes simplex keratitis, Smallpox, Chickenpox / Herpes Zoster, or any other viral infection of the eye
 - Fungal diseases of the eye or an untreated parasitic eye infection
 - Tuberculosis of 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 Suspension is not recommended during pregnancy or breast-feeding.

- Before you start to use it

- If you experience allergic reactions with Maxitrol Suspension, 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 Suspension 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 Suspension especially if you have diabetes.
 - Develop cataract
 - Become more susceptible to eye infections
 - 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
- Ritonavir or cobicistat (used to treat AIDS/HIV)

How to use Maxitrol Suspension

- How much to use

1 to 2 drops in the conjunctival sac 4 to 6 times daily. In severe disease, drops may be used hourly, being tapered to discontinuation as the inflammation subsides.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

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

- If you forget to use it

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.

- If you use too much (overdose)

If you use more Maxitrol Suspension than you should, rinse it all out with warm water. Do not put in any more drops 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.
- After cap is removed, if tamper evident snap collar is loose, remove before using product.
- Only use Maxitrol Suspension for dropping in your eye(s).
- Keep the eyelid closed, while simultaneously applying gentle pressure to the lachrymal canal (tear duct) with a finger to limit the amount of medicine that will come into the blood after application of the eye drops.

- Things you must not do

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 Suspension to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- If a drop misses your eye, try again.
- A preservative in Maxitrol Suspension (benzalkonium chloride) may cause eye irritation and is also known to discolor soft contact lenses. If your healthcare provider considers that you can use contact lenses, you should remove them before using Maxitrol Suspension and wait at least 15 minutes before putting your lenses back in.

- 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.

Driving and using machines

You may find your vision is blurred for a time after you use Maxitrol Suspension. Do not drive or use machines until this has worn off.

Side effects

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

- 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 receiving systemic neomycin or when applied topically to open wounds or damaged skin. Toxicity to the nerve and kidney have also occurred with systemic polymyxin B. Although these effects have not been reported following this eye product,

caution is advised when used concomitantly with systemic aminoglycoside or polymyxin B therapy. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Maxitrol Suspension

- Storage

Store below 30°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 ophthalmic suspension

Opaque, white to pale yellow suspension, no sediments

- Ingredients

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

- Inactive ingredients
Polysorbate 20 (E432), sodium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH), benzalkonium chloride, hypromellose (E464) and purified water.

- MAL number:

MAL19890183ACRZ

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Product Registration Holder

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