

MAXITROL™ Eye Ointment

Dexamethasone, Neomycin and Polymyxin B

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Read this leaflet carefully before you start to use Maxitrol Eye Ointment.

This leaflet answers some common questions about Maxitrol Eye Ointment. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.medsafe.govt.nz.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Maxitrol against the expected benefits it will have for you.

The information in this leaflet applies to Maxitrol Eye Ointment only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Maxitrol Eye Ointment is used for

Maxitrol Eye Ointment is a sterile eye ointment that contains the active ingredients dexamethasone, neomycin and polymyxin B. Both neomycin and polymyxin B are antibiotic agents. Dexamethasone is a type of cortisone and belongs to the group of medicines called corticosteroids.

Maxitrol Eye Ointment is used to treat inflammation and bacterial infections in the external part of the eye.

Before prescribing Maxitrol Eye Ointment, your doctor will have examined your eye(s) and decided that Maxitrol Eye Ointment is the right medicine for you.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed Maxitrol Eye Ointment for another reason.

This medicine is only available with a doctor's prescription

There is no evidence that Maxitrol Eye Ointment is addictive.

Use in children

Maxitrol Eye Ointment is not recommended for use in children as the safety and effectiveness in children has not been established.

Before you use Maxitrol Eye Ointment

When you must not use it

Do not use Maxitrol Eye Ointment if you have an allergy to:

- neomycin or other aminoglycoside antibiotics
- polymyxin B or other polymyxin antibiotics
- dexamethasone or any other corticosteroid medicine
- any of the ingredients in Maxitrol Eye Ointment listed under *Product Description* at the end of this leaflet
- other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use Maxitrol Eye Ointment if:

- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed.

If you use this medicine after the expiry date has passed, it may not work.

Contact lens wear is not recommended during treatment of an eye infection. Avoid the use of Maxitrol Eye Ointment while you are wearing contact lenses.

Maxitrol Eye Ointment is not to be used if you have an ocular viral or fungal infection or have had a foreign body removed from the outside of the eye.

If you are not sure whether you should start using Maxitrol Eye Ointment, talk to your doctor.

Before you start to use it

Tell your doctor if you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions including:

- disease(s) that causes thinning of the cornea (the front layer of the eye ball) or

sclera (the white outer layer of the eyeball).

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you use Maxitrol Eye Ointment.

Using other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including other eye drops or ointments, and any other medicines that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Maxitrol Eye Ointment may interfere with each other. These medicines may be affected by Maxitrol Eye Ointment, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Tell your doctor or pharmacist if

- you are using non-steroidal anti-inflammatory (NSAIDs) medicines in your eyes
- you are using medicines to treat viral infections e.g. ritonavir or cobicistat

Your doctor or pharmacist has more information on medicines

to be careful with or avoid while using this medicine.

How to use Maxitrol Eye Ointment

Use Maxitrol Eye Ointment only as prescribed by your doctor.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to use

The usual dosage for Maxitrol Eye Ointment is to **apply a small amount to the eye up to three or four times daily.**

Your doctor will tell you how much you need to use each day. These dosing instructions will be printed on the label your pharmacist puts on the tube or carton.

How to use it

It is important to use Maxitrol Eye Ointment exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and the eye problem may not improve. Using it more often than you should may not improve the eye problem any faster and may cause increased side effects.

Follow these steps to use the eye ointment:

1. Wash your hands thoroughly with soap and water.
2. Remove the cap from the tube. Using the forefinger, gently pull your lower

eyelid down to form a pouch (see Diagram 1).



Diagram 1

- Using your other hand, carefully squeeze a small ribbon (about 1 – 1.5 cm) of ointment into the pouch (see Diagram 2).



Diagram 2

- Making sure that the ointment remains within the eye, slowly close your eye without blinking (see Diagrams 3 and 4). Keep your eye closed for 1 to 2 minutes.



Diagram 3



Diagram 4

- If necessary, repeat the above steps 1-4 for your other eye.

- Place the cap on the tube and close it tightly.
- Wash hands again with soap and water to remove any residue.

You may feel a slight burning sensation in the eye shortly after using Maxitrol Eye Ointment. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the tip of the tube against your fingers or the eye, or anything else.

This will help prevent the ointment becoming dirty or contaminated.

How long to use it

Your doctor or pharmacist will tell you how long to use Maxitrol Eye Ointment.

Do not use Maxitrol Eye Ointment for longer than your doctor tells you.

If you use Maxitrol Eye Ointment for longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are not sure how long to use Maxitrol Eye Ointment, talk to your doctor or pharmacist.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use the eye Ointment as soon as you remember, and then go back to using them as you would normally.

Do not use a double dose to

make up for the application that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put too much ointment in your eye(s) immediately rinse your eye(s) with lukewarm water.

If you think that you or someone else has swallowed Maxitrol Eye Ointment, or used too much ointment immediately telephone your doctor or the National Poisons Centre on 0800 POISON or 0800 764 766 for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

While you are using Maxitrol Eye Ointment

Things you must do

If you feel that Maxitrol Eye Ointment is not helping your condition, tell your doctor (or pharmacist). If your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using Maxitrol Eye Ointment.

Tell all the doctors, dentists

and pharmacists who are treating you that you are using Maxitrol Eye Ointment.

Tell your doctor if, for any reason, you have not used Maxitrol Eye Ointment exactly as prescribed. Otherwise your doctor may think that it was not effective and change the treatment unnecessarily.

Tell your doctor if you experience swelling and weight gain around the trunk and in the face, it may be symptoms of a hormonal imbalance known as Cushing's syndrome. Talk to your doctor before stopping the treatment by yourself. Stopping long term or intensive treatment with Maxitrol may cause your adrenal glands to not work properly. These risks are especially important in children and patients treated with medicine containing ritonavir or cobicistat.

Immediately tell your doctor if you become pregnant while using Maxitrol Eye Ointment.

Keep all your doctor's appointments so that your doctor can check on your progress. Your doctor may need to check your eye pressure whilst you are using Maxitrol Eye Ointment.

Things you must not do

Do not let children handle Maxitrol Eye Ointment

Do not use Maxitrol Eye Ointment to treat any other complaints unless your doctor tells you to.

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

Do not stop using Maxitrol Eye Ointment or lower the dosage

because you are feeling better, unless advised by your doctor.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using Maxitrol Eye Ointment.

Things to be careful of

Be careful driving or operating machinery until you know how Maxitrol Eye Ointment affect you and your vision.

As with any eye medicine, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, wait until your vision is clear before driving or using machinery.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are using Maxitrol Eye Ointment.

Maxitrol Eye Ointment helps most people with inflammation and bacterial infections but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Eye irritation, discomfort or feeling of having something in the eye
- Eye pain
- Inflammation of the cornea (clear front portion of your eye) (keratitis)
- Swollen, itchy eyes or eyelids
- Eye redness
- Increased tearing
- Blurred vision
- Drooping eyelid
- Dilated pupil
- Increased sensitivity to sunlight
- Secondary eye infection
- Raised pressure in the eye which may lead to headaches and disturbances of vision.
- Delayed healing of any eye wounds.

In some rare cases, the development of glaucoma (a condition of the eye in which the pressure of fluid in the eye may be high, however some people with glaucoma may have normal pressure) with optic nerve damage (the nerve that connects the eye to the brain) has been reported.

If any of the following happen, stop using Maxitrol Eye Ointment and call your doctor immediately or go to Accident and Emergency at your nearest hospital:

- skin rash
- swelling of the face (lips, mouth, tongue, throat), hands or feet

- wheezing, difficulty in breathing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash
- shortness of breath, chest pain, dizziness, light-headedness.

These hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some people.

After using Maxitrol Eye Ointment

Storage

Store Maxitrol Eye Ointment in a cool dry place where the temperature stays below 25°C. Do not refrigerate.

Do not store Maxitrol Eye Ointment or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and a half meters above the ground is a good place to store medicines.

Disposal

Write the date on the carton when you first open the eye ointment. Throw out any remaining ointment after four weeks from opening.

Maxitrol Eye Ointment contains preservatives which help prevent germs growing in the ointment for the first four weeks after opening the tube. After this time there is a greater risk that the ointment may become contaminated and cause an eye infection. A new tube should be opened.

If your doctor tells you to stop using Maxitrol Eye Ointment or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Maxitrol Eye Ointment comes in a 3.5 g tube with screw cap.

Ingredients

Active ingredients:

- dexamethasone (1.0 mg/g)
- neomycin sulfate (3500 IU/g)
- polymyxin B sulfate (6000 IU/g)

It also contains:

- methyl hydroxybenzoate as a preservative
- propyl hydroxybenzoate as a preservative
- anhydrous liquid lanolin
- white soft paraffin.

Supplier

Maxitrol Eye Ointment is supplied in New Zealand by:

Novartis New Zealand Limited
PO Box 99102

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335

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