

MAXITROL™ Eye Drops

Dexamethasone, Neomycin and Polymyxin B

CONSUMER MEDICINE INFORMATION

What is in this leaflet

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

This leaflet answers some common questions about Maxitrol Eye Drops. 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 Drops 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 Drops is used for

Maxitrol Eye Drops is a sterile eye drop 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 Drops are used to treat inflammation and bacterial infections in the external part of the eye.

Before prescribing Maxitrol Eye Drops, your doctor will have examined your eye(s) and decided that Maxitrol Eye Drops 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 Drops for another reason.

This medicine is only available with a doctor's prescription

There is no evidence that Maxitrol Eye Drops are addictive.

Use in children

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

Before you use Maxitrol Eye Drops

When you must not use it

Do not use Maxitrol Eye Drops 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 Drops 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 Drops if:

- the safety seal around the closure and neck area is broken
- the bottle/packaging shows signs of tampering
- the expiry date on the bottle/carton 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.

The preservative in Maxitrol Eye Drops, benzalkonium chloride, may cause eye irritation and is known to discolour contact lenses.

Maxitrol Eye Drops 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 Drops, 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 Drops.

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 Drops may interfere with each other. These medicines may be affected by Maxitrol Eye Drops, 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 Drops

Use Maxitrol Eye Drops 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 dose is **1 to 2 drops** in the affected eye(s) **up to 4 to 6 times daily**. Your doctor may increase the dose to **1 to 2 drops** in the affected eye(s) **every hour** depending on your condition.

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 bottle or carton.

How to use it

It is important to use Maxitrol Eye Drops 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 drops:

1. Wash your hands thoroughly with soap and water.
2. Immediately before using a bottle for the first time, break the safety seal around

the neck area and throw the loose plastic ring away.

3. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

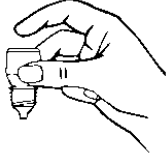


Diagram 1

5. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch / pocket.
6. Place the tip of the bottle close to your eye. Do not let it touch your eye.
7. Release one drop into the pouch / pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (see Diagrams 2 and 3). Do not squeeze the bottle.
- 8.

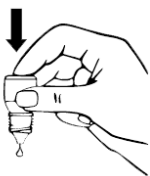


Diagram 2



Diagram 3

9. Close your eye. Do not blink or rub your eye.
10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. This will also reduce the unpleasant taste sensation that some people experience when using these drops.
11. If necessary, repeat the above steps for the other eye.
12. Your eyelids can only hold less than one drop at a time, so it is normal for a small amount of the eye drop to spill onto your cheek. You should wipe away any spillage with a tissue.
13. Replace the cap on the bottle, closing it tightly.
14. Wash your 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 Drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the tip of the bottle against your fingers or the eye, or anything else. This will help prevent the eye drops becoming dirty or contaminated.

After using Maxitrol Eye Drops, wait at least 5 minutes before putting any other eye drops in your eye(s).

How long to use it

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

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

If you use Maxitrol Eye Drops 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 Drops, 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 drops 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 eye drops 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 many eye drops in your eye(s) immediately rinse your eye(s) with lukewarm water.

If you think that you or someone else has swallowed Maxitrol Eye Drops, 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 Drops

Things you must do

If you feel that Maxitrol Eye Drops 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 Drops.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Maxitrol Eye Drops.

Tell your doctor if, for any reason, you have not used Maxitrol Eye Drops 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.

Tell your doctor immediately if you become pregnant while using Maxitrol Eye Drops.

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 Drops.

Things you must not do

Do not let children handle Maxitrol Eye Drops.

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

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

Do not stop using Maxitrol Eye Drops 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 Drops.

Things to be careful of

Be careful driving or operating machinery until you know how Maxitrol Eye Drops 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 Drops.

Maxitrol Eye Drops help 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 Drops 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 Drops

Storage

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

Do not store Maxitrol Eye Drops 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 bottle when you first open the eye drops and throw out any remaining drops after four weeks.

Maxitrol Eye Drops contains a preservative which helps prevent germs growing in the suspension for the first four weeks after opening the bottle. After this time there is a greater risk that the suspension may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using Maxitrol Eye Drops 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 Drops comes in a 5 mL Drop-Tainer with screw cap.

Tamper evidence is provided with a safety seal around the neck area of the bottle.

Ingredients

Active ingredients:

- dexamethasone 1 mg in 1 mL
- neomycin sulfate 3500 IU in 1 mL
- polymyxin B sulfate 6000 IU in 1 mL.

It also contains:

- benzalkonium chloride (0.04 mg/mL) as preservative
- hypromellose
- polysorbate 20
- sodium chloride
- sodium hydroxide and/or hydrochloric acid (to adjust pH)
- purified water.

Supplier

Maxitrol Eye Drops are supplied in New Zealand by:

Novartis New Zealand Limited

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335.

Date of preparation

This leaflet was prepared in July 2020.

TM trademark.