

Package Leaflet - Information for the User
MAXITROL® 0.1 % w/v, 6000 IU/ml, 3500 IU/ml eye drops, suspension
dexamethasone, polymyxin B sulphate, neomycin sulphate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you..

- **Keep this leaflet.** You may need to read it again.
- **If you have any further questions,** ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. **Do not pass it on to others.** It may harm them, even if their signs of illness are the same as yours.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. **What MAXITROL is and what it is used for**
2. **What you need to know before you use MAXITROL**
3. **How to use MAXITROL**
4. **Possible side effects**
5. **How to store MAXITROL**
6. **Contents of the pack and other information**

1. What MAXITROL is and what it is used for

MAXITROL contains a steroid, dexamethasone and two antibiotics, neomycin sulphate and polymyxin B sulphate.

It is used for the short term treatment of inflammation of the eye, where administration of an antibiotic is also required to prevent an eye infection.

2. What you need to know before you use MAXITROL

Do not use MAXITROL...

- If you have **any type of infection** of the eye that is not being treated including viral, fungal or untreated parasitic eye infections or Tuberculosis of the eye. Use of steroids may make infections worse.
- If you are **allergic** to dexamethasone, polymyxin B, neomycin or to any of the other ingredients listed in section 6.

Ask your doctor for advice.

Take special care...

- Only use MAXITROL in your eye(s).
- Consult your doctor or pharmacist before using this medicine if you have a disorder causing a **thinning of the eye tissues.**
- If you experience **allergic reactions** with MAXITROL, 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 topical or systemic antibiotics of the same family (aminoglycosides).
- Consult your doctor or pharmacist if your symptoms get worse or persist. You may become more susceptible to eye infections with the use of this product.
- Steroids applied to the eye may delay the healing of your eye wound. Topical NSAIDs (Non-Steroidal Anti Inflammatory Drugs-Medications) are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- If you are using **other antibiotics** (including oral) with MAXITROL, consult your doctor for advice.

- If you use MAXITROL for a **long period** of time, you may:
 - Become more susceptible to other eye infections
 - Have increased pressure in your eye(s). You should have your eye pressure checked regularly while using MAXITROL. This is especially important in children, as the risk of corticosteroid-induced increased pressure in the eye may be greater in children and may occur earlier than in adults. The risk of corticosteroid-induced increase intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).
 - Develop cataracts.
 - 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 a syndrome called Cushing's syndrome. Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with MAXITROL. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat.
 - Contact your doctor if you experience blurred vision or other visual disturbances.

If any of these apply, you may still be able to use MAXITROL, but discuss it with your doctor first.

Other medicines and Maxitrol

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Taking MAXITROL with other medicines may increase the seriousness of any side effects.

Especially tell your doctor if you are using:

- Topical NSAIDs. Concomitant use of topical steroids and topical NSAIDs may increase corneal healing problems.
- Tell your doctor if you are using ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.

Pregnancy and breast-feeding and fertility

MAXITROL is **not recommended** during pregnancy or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, **ask your doctor** or pharmacist for advice before taking this medicine.

Driving and using machines

You may experience blurred vision after using MAXITROL. **Do not drive or use any machines unless your vision is normal.**

Important information if you wear Contact Lenses

Wearing contact lenses is **not advisable** during the treatment of an eye infection, as they may make your condition worse. If you do continue to wear your lenses, you must remove them before using MAXITROL and wait at least 15 minutes after use before putting your lenses back in.

This medicine contains 0.2 mg Benzalkonium Chloride in each 5 ml which is equivalent to 0.04 mg/ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use MAXITROL

The usual dose

The usual dose is 1 or 2 drops into the space between your eyelid and eye 6 times daily, or more frequently if required.

Remove the loose collar from the cap when the bottle is first opened.

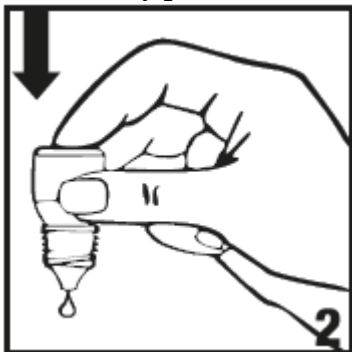
Always use MAXITROL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. MAXITROL should not be used for a long period of time unless advised by your doctor.

How to use

- Wash your hands before you start.
- **Shake the bottle well.**
- Twist off the bottle cap.
- Hold the bottle pointing down, between your thumb and fingers. Tilt your head back.
- Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).



- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- **Do not touch your eye or eyelid**, surrounding areas or other surfaces with the dropper. It could infect the drops.
- **Gently press on the base** of the bottle to release one drop at a time (picture 2).



- **Do not squeeze the bottle**, only a gentle press on the bottom is needed.
- After using MAXITROL, keep the eyelid closed, while applying gently pressure to the corner of your eye by the nose (picture 3). This helps to reduce the amount of medicine getting into the rest of the body.



- If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.
- **If a drop misses your eye**, try again.
- **If you forget to take MAXITROL**, do not worry, just take it as soon as possible. **Do not take a double dose to make up.**
- **If you use more MAXITROL than you should** it can be washed out of your eye with warm water.
- **If you are using other eye drops or eye ointments**, wait at least 5 minutes after putting in MAXITROL before using the other medicine. Eye ointments should be administered last.

If you have any further questions on the use of MAXITROL, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, MAXITROL can cause side effects, although not everybody gets them.

You may experience some or all of the following effects in your eye:

Uncommon (*affect 1 to 10 users in 1000*):

- eye surface inflammation,
- increased pressure in the eye,
- eye irritation,
- itching or
- discomfort.

Not known (*cannot be estimated from the available data*):

- 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,
- thinning of the surface of the eye.

You may also experience side effects in other parts of your body:

Not known (*cannot be estimated from the available data*):

- allergy,
- headache,
- serious skin reactions (Stevens-Johnson syndrome),
- hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children

and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance,

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MAXITROL

Keep this medicine out of the sight and reach of children.

Do not refrigerate or freeze

Do not store above 25 °C.

Store in the original package to protect from light.

Keep the container tightly closed.

Do not use the drops after the expiry date (marked 'Exp') on the bottle and the carton. The expiry date refers to the last day of that month.

Stop using the bottle 4 weeks after first opening, to prevent infections.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.

6. Contents of the pack and other information

What MAXITROL contains

- The active substances are dexamethasone 1 mg/ml, polymyxin B sulphate 6000 IU/ml, neomycin sulphate (as base) 3500 IU/ml.
- The other ingredients are sodium chloride, polysorbate 20, hypromellose, benzalkonium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water.

What MAXITROL looks like and contents of the pack

MAXITROL Eye Drops is a cloudy, white liquid supplied in a pack containing a 5 ml plastic bottle with a screw cap.

Marketing Authorisation Holder:

Novartis Ireland Ltd
Vista Building
Elm Park
Ballsbridge
Dublin 4
Ireland

Manufacturer:

Novartis Pharma GmbH
Roonstrasse 25,
D-90429 Nurnberg,

Germany

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