Package Leaflet - Information for the User

MAXITROL* eye drops, suspension
Dexamethasone, Neomycin sulphate, Polymyxin B sulphate

Read all of this leaflet carefully before you start using this medicine
- **Keep this leaflet.** You may need to read it again.
- **If you have any further questions,** ask your doctor or pharmacist.
- This medicine has been prescribed for you. **Do not pass it on to others.** It may harm them, even if their signs of illness are the same as yours.
- **If any of the side effects get serious,** or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 have a **red eye** that has not been seen by a doctor.
- If you are **allergic** to dexamethasone, neomycin, polymyxin B or to any of the other ingredients listed in section 6.

Ask your doctor for advice.

Take special care...
- Do not inject or swallow this medicine.
- Consult your doctor or pharmacist before using this medicine if you have a disorder causing a **thinning of the eye tissues.**
- Consult your doctor or pharmacist if your eye pain, redness, swelling, or irritation gets worse or persists. You may become more susceptible to eye infections with the use of this product.
- 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).
- 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.

Simultaneous use of topical NSAIDs and topical steroids may increase the potential for healing problems.

- If you use MAXITROL 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. 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 cataract
    - Become more susceptible to eye infections
- 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.
- Talk to your doctor before using Maxitrol if you have diabetes or have a family history of diabetes.

Pregnancy and breast-feeding
MAXITROL is **not recommended** during pregnancy or breast-feeding. If you are pregnant or might get pregnant, or if you are breast-feeding a baby, **talk to your doctor** before you use MAXITROL.

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

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 the side effects.

Especially tell your doctor if you are using:
- Topical NSAIDs. Simultaneous use of topical steroids and topical NSAIDs may increase healing problems in your eye.

Tell your doctor if you are using ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.

Tell your doctor if you are diabetic and you are taking, having recently taken or might take medicines for treatment of diabetes such as insulin, metformin or sulfonylureas such as chlorpropamide, as Maxitrol may decrease the blood glucose lowering effect of these medicines

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. There is a preservative in MAXITROL (benzalkonium chloride).

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 recommended dose
The recommended 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.

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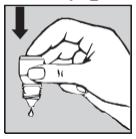
How to use
- Wash your hands before you start.
- **Shake the bottle well.**
- Twist off the bottle cap.
- Hold the bottle pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop 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,** wait at least 5 minutes after putting in MAXITROL before using the other eye drops. 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 eyes:

Uncommon (affect 1 to 10 users in 1000):
eye surface inflammation, increased pressure in 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 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"). Steroids may be associated with an increase of blood glucose levels and diabetes.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store MAXITROL

- Keep out of the reach and sight of children.
- Do not refrigerate or store above 25°C.
- Keep the bottle tightly closed.
- Keep away from direct sunlight.
- 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, neomycin sulphate 3500 IU/ml, polymyxin B sulphate 6000 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 8 ml or 10 ml plastic bottle with a screw cap.

Marketing authorisation holder:
Novartis Pharmaceuticals UK Limited,
2nd Floor, The WestWorks Building, White City Place,
195 Wood Lane,
London,
W12 7FQ
United Kingdom.

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