

## Package Leaflet: Information for the User

### MAXITROL®

#### 0.1% w/w, 6000 IU/g, 3500 IU/g eye ointment

Dexamethasone, Polymyxin B sulphate, Neomycin 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 your pharmacist.
- This medicine has been prescribed for you. **Do not pass it on to others.** It may harm them, even if their symptoms 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.

### IN THIS LEAFLET

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#### 1. WHAT MAXITROL OINTMENT IS AND WHAT IT IS USED FOR

**MAXITROL Ointment** 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, when it is also considered that a bacterial eye infection could develop.

#### 2. BEFORE YOU USE MAXITROL OINTMENT

**Do not use MAXITROL Ointment...**

- 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 Ointment 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 any 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 Ointment, consult your doctor for advice.
- If you use MAXITROL Ointment 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).
  - Become more susceptible to other eye infections.
  - Develop cataract.
  - 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 Ointment, but discuss it with your doctor first.

#### **Pregnancy and breast-feeding**

MAXITROL Ointment 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 Ointment.

#### **Driving and using machines**

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

#### **Using other medicines**

**Tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Taking MAXITROL Ointment 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.

#### **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.

#### **Important information about some of the ingredients in MAXITROL Ointment**

MAXITROL Ointment contains lanolin which may cause local skin reactions. MAXITROL Ointment contains parahydroxybenzoates which can cause allergic reactions.

### **3. HOW TO USE MAXITROL® OINTMENT**

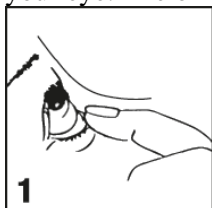
#### **The usual dose**

The usual dose is to apply MAXITROL Ointment 3-4 times daily. The ointment may also be used at bedtime, while eye drops are used during the day.

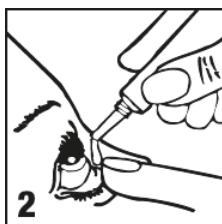
Always use MAXITROL Ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### How to use

- Wash your hands before you start.
- Remove the cap from the tube.
- Tilt your head back.
- Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The ointment will go in here (picture 1).



- Bring the ointment tube 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 tip of the tube. It could infect the ointment.
- Gently squeeze a small ribbon of ointment into the pocket formed between your lower eyelid and your eye (picture 2).



- Release the lower eyelid and blink a few times.
- If you use ointment in both eyes, repeat the steps for your other eye. Replace and tightly close the cap on the tube.
- **If you miss a dose** do not worry, just apply the next dose when it is due. **Do not use a double dose to make up.**
- **If you use more MAXITROL Ointment than you should** do not worry, it is not likely to do any harm.
- **If this medicine is accidentally swallowed** it is not likely to cause any serious problems.
- **If you are using other eye drops or eye ointment**, wait at least 5 minutes after putting in the other medicine before applying MAXITROL Ointment.

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

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## 4. POSSIBLE SIDE EFFECTS

Like all medicines, MAXITROL<sup>®</sup> Ointment 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 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 effects in other parts of your body:**

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

allergy, headache, serious skin reactions (Steven-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,

Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie);

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

## **5. HOW TO STORE MAXITROL OINTMENT**

- Keep out of the reach and sight 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 ointment after the expiry date (marked 'Exp') on the tube and the carton. The expiry date refers to the last day of that month.
- **Stop using the tube 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. FURTHER INFORMATION**

### **What MAXITROL Ointment contains**

- The active substances are Dexamethasone 1 mg/g, Polymyxin B sulphate 6000 IU/g, Neomycin sulphate (as base) 3500 IU/g.
- The other ingredients are methyl parahydroxybenzoate, propyl parahydroxybenzoate, liquid lanolin and white soft paraffin.

### **What MAXITROL Ointment looks like and contents of the pack**

MAXITROL Ointment is a white to very pale yellow ointment supplied in a pack containing a 3.5 g metal tube with a screw cap.

### **Marketing authorisation holder :**

Alcon Laboratories (UK) Ltd.

Frimley Business Park, Frimley,  
Camberley, Surrey, GU16 7SR,  
United Kingdom

**Manufacturer :**

Alcon Cusi, S.A.  
08320 El Masnou - Barcelona,  
Spain.

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**Alcon a Novartis company**