

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### MAXITROL

Eye drops, suspension

DEXAMETHASONE, NEOMYCIN SULPHATE, POLYMYXIN B SULPHATE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 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 •*

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#### What is in this leaflet?

1. What MAXITROL is and what it is used for
2. Before you take MAXITROL
3. How to take MAXITROL
4. Possible side effects
5. How to store MAXITROL
6. Further information

#### 1. WHAT MAXITROL IS AND WHAT IS IT 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. BEFORE YOU TAKE MAXITROL

##### **Do not use MAXITROL**

- If you have **any type of infection** of the eye that is not being treated. 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 neomycin 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.
- You should have your eye pressure checked regularly while using this medicine. This is especially important for children.
- The risk of increase in eye pressure and / or cataract formation is higher in susceptible patients ( e.g. patients with diabetes ) using steroids.
- Consult your doctor or pharmacist if your eye pain, redness, swelling, or irritation gets worse or persists.
- 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.
- As with any antibiotic, use of MAXITROL for a long time may lead to other infections. If your symptoms get worse or suddenly return tell your doctor.

### ***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.**

### ***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 with other medicines may increase the seriousness of the side effects. Tell your doctor if you are using topical NSAIDs. Simultaneous use of topical steroids and topical NSAIDs may increase healing problems in your eye.

### ***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.

There is a preservative in MAXITROL ( benzalkonium chloride ) that can discolour soft contact lenses.

## ***3. HOW TO TAKE 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.
- 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, blurred vision, sensitivity to light, change in pupil size, drooping of eye lid, eye pain, swelling or redness, eye irritation, itching or discomfort, abnormal eye sensation, increased tear production,

Thinning of the surface of the eye has also been reported. It is not known how many users may have experienced this side effect.

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

Hypersensitivity or general allergy to MAXITROL and headache have been reported. It is not known how many users may have experienced these side effects

#### 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.

#### 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. FURTHER 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 5 ml or 10 ml plastic bottle with a screw cap.

### **Manufacturer**

SA Alcon-Couvreur NV, Rijksweg 14, B-2870 Puurs, Belgium