

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

This medicine is dispensed with a doctor's prescription only.

# Maxitrol Ophthalmic Ointment

## Composition:

Each gram of ointment contains:

Dexamethasone 1 mg

Neomycin Sulphate 3,500 I.U.

Polymyxin B Sulphate 6,000 I.U.

Inactive ingredients appear in section 6 - "Further Information". Also see "Important information about some of the ingredients of the medicine" in section 2.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet. You may need to read it again.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is used to treat eye infections that respond to steroid treatment, when antibiotic treatment is also needed.

**Therapeutic group:** Anti-infective. For ocular use.

Dexamethasone: synthetic glucocorticoid

Neomycin sulphate: aminoglycoside antibiotic

Polymyxin B sulphate: polymyxin antibiotic

## 2. BEFORE USING THE MEDICINE:

### ☒ Do not use the medicine if:

- You have any untreated infection in the eye including a viral, fungal or untreated parasitic eye infection or tuberculosis of the eye. Use of steroids may worsen the infection.
- You have a sticky discharge from the eye.
- You are sensitive (allergic) to dexamethasone, neomycin sulphate, polymyxin B sulphate or to any of the other ingredients contained in the medicine and that appear in section 6 - "Further Information".

Consult the doctor.

### Special warnings regarding use of Maxitrol Ophthalmic Ointment:

- Use of Maxitrol Ophthalmic Ointment is for the eyes only. Do not inject or swallow the medicine.

### ☒ Before treatment with Maxitrol Ophthalmic Ointment, tell the doctor if:

- Consult the doctor before using the medicine if you are suffering from any disease that causes **thinning/atrophy of the eye tissues**.
- Consult the doctor if the eye pain, eye redness, swelling of the eye or eye irritation worsens or does not pass.
- You experience allergic reactions with Maxitrol, discontinue use and consult the doctor. Allergic reactions may vary from localized itching or localized 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 administered to the eye may delay healing of the eye sore. Non-steroidal anti-inflammatory drugs (NSAIDs) may also slow or delay healing. Concomitant administration of topical NSAIDs and topical steroids may increase the risk of problems in the healing of the eye.
- If you use Maxitrol Ophthalmic Ointment for a long time, you may:
  - Experience increased intraocular pressure. Check your intraocular pressure regularly while using Maxitrol. This is especially important in children, as the risk of increased intraocular pressure following corticosteroid use may be higher in children and may occur earlier than in adults. The risk of increased intraocular pressure due to corticosteroid use and/or cataract formation is higher in patients with a predisposition (e.g., diabetics).
  - Develop a cataract.
  - Become more susceptible to eye infections.
- Consult the doctor if you experience swelling and weight gain in the trunk and face, as these are usually the first manifestations of a syndrome called Cushing's syndrome. Suppression of adrenal gland activity may develop after stopping a long-term and intensive treatment with Maxitrol Ophthalmic Ointment. These risks are especially important in children and patients treated with drugs called ritonavir or cobicistat.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Before using Maxitrol Ophthalmic Ointment, tell the doctor if you have diabetes or have a family history of diabetes.

### ☒ Pregnancy and breastfeeding:

Use of Maxitrol Ophthalmic Ointment during pregnancy and breastfeeding is not recommended. If you are pregnant or planning a pregnancy, or if you are breastfeeding, consult the doctor before using Maxitrol Ophthalmic Ointment.

### ☒ Driving and use of machines:

Maxitrol Ophthalmic Ointment may cause temporary blurred vision during use. **If your vision is affected in any way, do not drive or operate machines.**

### ☒ Drug interactions:

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Taking Maxitrol with other medicines may increase the severity of side effects. In particular, inform the doctor or pharmacist if you are taking:

- non-steroidal anti-inflammatory drugs (NSAIDs) for topical use, since concomitant use of topical steroids and topical NSAIDs may cause problems in healing of the cornea.
- ritonavir and cobicistat, as it may raise the levels of dexamethasone in your blood.
- Tell the doctor if you are a diabetic and if you are taking, have recently taken or may take medicines for treatment of diabetes such as insulin, metformin, sulfonylureas such as chlorpromamide, as Maxitrol Ophthalmic Ointment may decrease the blood glucose lowering effect of these medicines.

### ☒ Important information if you wear contact lenses:

Wearing contact lenses is not advisable during treatment of an eye infection, as it may worsen the condition. If, despite this, you wear contact lenses during the course of treatment, remove them before using Maxitrol Ophthalmic Ointment and wait at least 15 minutes before putting the lenses back into the eyes.

### ☒ Important information about some of the ingredients of the medicine:

Maxitrol Ophthalmic Ointment contains the ingredients:

- Lanolin, which may cause a local skin reaction, such as contact dermatitis.
- Methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause an allergic reaction, possibly delayed.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain regarding the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally: a small amount (a "strip" of one to one and a half centimeters) 3 to 4 times a day or once before bedtime when using other eye drops during the day.

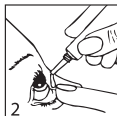
### Do not exceed the recommended dose.

Do not swallow! This medicine is intended for external use only.

Use this medicine at set intervals, as determined by the attending doctor.

### Instructions for use:

- To avoid contamination of the ointment, do not allow the tip of the tube to come into contact with any surface (including the eye itself). After use, wipe the tip of the ointment tube with a clean tissue and then tightly close the tube.
- How to use the ointment: First, wash your hands thoroughly. Remove the cap from the tube. Tilt your head back and pull down the lower eyelid to form a "pocket" (Figure 1). Gently squeeze the ointment tube. A small amount (a "strip" of one to one and a half centimeters) of ointment is generally enough, unless you received other instructions from the doctor or pharmacist. Instill the ointment into the gap that has formed (Figure 2). Release the lower eyelid and blink a few times. Close your eyes gently for approximately 1-2 minutes.
- After using the ophthalmic ointment, wash your hands to clean them from remnants of the medicine.



If you have to use the ointment in both eyes, repeat the above instructions in the other eye as well.

If you are using more than one type of eye drops or eye ointment, wait at least 5 minutes after using other medicines and before using Maxitrol Ophthalmic Ointment.

**If you forgot to take the medicine** at the required time, do not take a double dose to compensate. Take the next dose at the regular time and consult the doctor.

If you took an overdose, it is unlikely to cause harm. If a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult with the doctor or pharmacist.**

## 4. SIDE EFFECTS:

As with any medicine, use of Maxitrol Ophthalmic Ointment may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

**You may experience some or all of the following side effects in your eyes:**

**Uncommon side effects - effects that occur in 1-10 in 1,000 users:**

eye surface inflammation, increased intraocular pressure, eye irritation, itching or discomfort.

**Side effects of unknown frequency (effects whose frequency has not yet been established):**

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 the body:**

**Side effects of unknown frequency (effects whose frequency has not yet been determined):**

allergy, headache, serious skin reactions (Stevens-Johnson syndrome).

Hormone problems: excessive growth of body hair (particularly in women), muscle weakness and wasting, purple stretch marks on skin of the body, increased blood pressure, irregular or missed periods, changes in the levels of protein and calcium in the body, stunted growth in children and teenagers and swelling and weight gain in the body and face (called "Cushing's syndrome") (see section 2, "Special warnings regarding use of Maxitrol Ophthalmic Ointment").

Steroids can cause an increase of blood glucose levels and diabetes.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.**

### Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not refrigerate. Do not freeze.
- Do not store above 25°C.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton/label. The expiry date refers to the last day of that month.
- To avoid contamination, stop using the tube 28 days after first opening.
- To help protect the environment, consult the pharmacist about how to dispose of medicines no longer in use.

## 6. FURTHER INFORMATION:

In addition to the active ingredients, the medicine also contains:

Anhydrous liquid lanolin, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, White soft paraffin.

What the medicine looks like and the contents of the package: An aluminium tube containing 3.5 grams of white to light yellow, homogeneous, oily ointment.

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 128 53 28210.

Revised in September 2020