**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**
The medicine is dispensed with a doctor's prescription only

# Maxitrol Ophthalmic Suspension

**Active ingredients and quantities per dosage unit:**
Each ml of suspension contains:
Steroid: Dexamethasone 1.0 mg
Antibiotic: Neomycin sulphate 3,500 I.U.
Antibiotic: 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?

Maxitrol Ophthalmic Suspension is used to treat eye inflammations when concomitant use of an antimicrobial component is necessary.
**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, parasitic eye infection or tuberculosis of the eye. Use of steroids may worsen the infection.
- You have a **red eye** that has not been examined by a doctor.
- You are **sensitive (allergic)** to one or more of the active ingredients 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:**
- Do not inject or swallow the medicine.
- Consult the doctor or pharmacist before using the medicine if you are suffering from any disease that causes **thinning of the eye tissues**.
- Consult the doctor if you are suffering from eye pain, eye redness, swelling of the eye, or eye irritation that worsens or does not pass. You may become more susceptible to eye infections with the use of this preparation.
- If you experience allergic reactions with Maxitrol, discontinue use and consult the doctor. Allergic reactions may vary from localized itching or skin redness to severe allergic reactions (anaphylactic reaction) or severe 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 wounds. Topical non-steroidal anti-inflammatory drugs (NSAIDs) are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the risk of problems in the healing of the eye.
- If you use Maxitrol Ophthalmic Suspension for a long period of time you may:
  - Experience increased intraocular pressure. Check your intraocular pressure regularly while using Maxitrol.
    The risk of increased intraocular pressure due to corticosteroid use and/or cataract formation is higher in predisposed patients (e.g., diabetes).
  - Develop cataract.
  - Become more susceptible to eye infections.
- Consult the 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 adrenal gland activity may develop after stopping a long-term and intensive treatment with Maxitrol. These risks are especially important in children and patients treated with medicines called ritonavir or cobicistat.
- Contact the doctor if you experience blurred vision or other visual disturbances.
- Before using Maxitrol, tell the doctor if you have diabetes or have a family history of diabetes.

**Children and adolescents:**
- The risk of increased intraocular pressure on use of corticosteroids may be higher in children and may occur earlier than in adults.
- Consult the doctor if your child experiences swelling and weight gain in the trunk of the body and in the face, which are generally early manifestations of Cushing's syndrome. Depression of the adrenal gland may develop after discontinuing long-term and intensive treatment with Maxitrol.

**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. Simultaneous use of topical steroids and topical NSAIDs may cause a problem with healing of the eye.
- Ritonavir and cobicistat, as this may increase the level of dexamethasone in the blood.

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

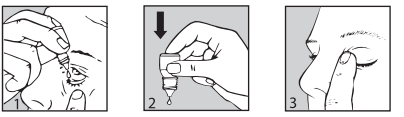
**Pregnancy and breastfeeding:**
Use of Maxitrol Ophthalmic Suspension during pregnancy or when breastfeeding is not recommended. If you are pregnant or are planning a pregnancy, or if you are breastfeeding, consult the doctor before using the medicine.

**Driving and use of machinery:**
You may experience blurred vision after using Maxitrol. **Do not drive or operate machines unless your vision is clear**.
Children should be warned against riding a bicycle or playing near the road, and the like.

**Important information about some of the ingredients of the medicine:**
Wearing contact lenses is **not advisable** during treatment of an eye infection, as this may worsen the condition.
The preparation contains a preservative (benzalkonium chloride). The preparation 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 discolor them. You should remove the contact lenses before using the preparation, and put them back 15 minutes after instilling the medicine into the eye.
Benzalkonium chloride may also cause eye irritation, especially if you are suffering from dry eyes or from disturbances of the cornea (the clear layer at the front of the eye). If you have an unusual sensation in the eyes, stinging or pain in the eye after using the medicine, refer to your doctor.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only. Recommended dosage: 1 or 2 drops in the space between the eyelid and the eye, 4 to 6 times a day, or more frequently as needed.
**Remove the loose collar** from the cap after first opening the bottle.
**Do not exceed the recommended dose.**
**Duration of treatment**
Do not use Maxitrol for a prolonged period unless recommended by the doctor.
**How to use**
Do not swallow. This medicine is intended for external use only.
Use this medicine at set intervals, as determined by the attending doctor.
**If you forgot to take this medicine at the designated time**, take a dose as soon as you remember. Do not take two doses together to compensate for a forgotten dose.
**Shake the bottle well before use.**
**Instructions for use:**
- In order to avoid contamination, do not allow the tip of the bottle to come into contact with any surface (including the eye itself). Keep the bottle tightly closed.
- The bottle of drops may not be full; this is to allow better control of the drip rate.
- Do not squeeze the bottle; pressing gently on the base of the bottle is enough to release the drop.
- How to use the drops: First, wash your hands. Tilt your head back. Using the index finger, pull down the lower eyelid to form a type of "pocket" between the eyelid and the eye (Figure 1). Instill the medicine into the "pocket" that has been formed (Figure 2). Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes.
- In addition to the above instructions – immediately after instilling the drops into the eye, press on the inner corner of the eye with the middle finger while the eyelid is closed (Figure 3). Continue pressing for 1 to 2 minutes after instilling into the eye. This action helps prevent absorption of the medicine into the body, thus helping to prevent side effects.
- After using the medicine, wash your hands thoroughly to clean them from remnants of the medicine.
- To avoid spreading infection, do not use the same bottle of medicine for more than one person.




If you did not manage to instill into the eye, try again.
If you are supposed to put a drop in the other eye, repeat the above instructions in the second eye as well.
**If you took an overdose**, the eye can be rinsed with warm water. If a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to the hospital emergency room, and bring the package of the medicine with you.
If you are using more than one kind of eye drops, wait at least 5 minutes between using Maxitrol Ophthalmic Suspension and other eye drops. Use eye ointments last.
Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.
**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 may cause side effects in some users. Do not be alarmed by 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 whose frequency is unknown (effects whose frequency has not yet been established):**
Corneal ulcer, blurred vision, sensitivity to light, increase in pupil size, eyelid drooping, eye pain, eye swelling, abnormal sensation in the eye, eye redness, increased tear production, thinning of the surface of the eye.
**You may experience effects in other parts of your body:**
**Side effects of unknown frequency (effects whose frequency has not yet been established):**
Allergy, headache, severe skin reactions (Stevens-Johnson syndrome).
Hormonal 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 missing periods, changes in the levels of protein and calcium in the body, stunted growth in children and teenagers, and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, 'Special warnings regarding use of Maxitrol').
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) 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, must be kept in a safe place out of the reach and sight 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 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.

**Storage conditions:**
- Do not store refrigerated.
- Do not store above 25°C.
- To avoid contamination, do not use the medicine for more than 28 days after first opening the bottle.
- To help protect the environment, consult a pharmacist about how to dispose of medicines that are no longer in use.

## 6. FURTHER INFORMATION:

In addition to the active ingredients, the medicine also contains: Sodium Chloride, Hypromellose, Polysorbate 20, Benzalkonium Chloride, Hydrochloric Acid and/or Sodium Hydroxide, Purified Water.
What the medicine looks like and the contents of the package:
A plastic bottle with a cap containing 5 ml of white to light yellow milky liquid, without lumps.
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: 116 23 22787
Revised in May 2021 according to MOH guidelines.