NOVARTIS

MAXITROL® Ophthalmic Suspension

Polymyxin B sulphate equal to 6000 international units polymyxin B base, neomycin sulphate equal to 3500 international units neomycin base and dexamethasone 1,0 mg per mL

MAXITROL® Ophthalmic Ointment

Polymyxin B sulphate equal to 6000 international units polymyxin B base, neomycin sulphate equal to 3500 international units neomycin base and dexamethasone 1,0 mg per gram

Patient Information Leaflet

Document status:	Final
Release date:	25 May 2022

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MAXITROL® Ophthalmic Suspension

MAXITROL® Ophthalmic Ointment

Dexamethasone, Neomycin sulphate, Polymyxin B sulphate

Read all of this leaflet carefully before you start using MAXITROL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MAXITROL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

What MAXITROL is:

MAXITROL contains a steroid, dexamethasone and two antibiotics, neomycin sulphate and polymyxin B sulphate.

What it is used for:

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 are hypersensitive (allergic) to dexamethasone, neomycin sulphate, polymyxin B sulphate or any of the other ingredients of MAXITROL;
- if you have or think that you have any type of infection of the eye e.g. Herpes simplex keratitis, Smallpox, Chickenpox / Herpes Zoster, or any other viral infection of the eye or an untreated parasitic eye infection or fungal diseases. Use of corticosteroids may make infections worse;
- if you have a sticky discharge from your eye;
- if you have a red eye that has not been seen by a doctor;
- if an uncomplicated foreign body was removed from your eye;
- if you have a cut or tearing of the eye that has not been seen by a doctor;
- if you have tuberculosis of the eye;
- if you are pregnant.

Warnings and precautions

Take special care with MAXITROL:

- if you have a disorder causing a thinning of the eye tissues, such as a corneal transplant. Corticosteroids may cause further thinning and possible perforation, and may delay the healing of your eye wound;
- Topical nonsteroidal anti-inflammatory drugs (NSAIDs) are also known to slow or delay healing. If you use topical NSAIDS and corticosteroids together, it may increase the potential for healing problems;
- 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 *(see section 4 Possible side effects*); These allergic reactions may occur with other topical or systemic antibiotics of the same family (aminoglycosides);
- if your symptoms get worse or suddenly return, please consult your doctor. You may become more susceptible to eye infections with the use of this product;
- if you are diabetic please consult your doctor. The risk of corticosteroid-induced increase intraocular pressure and/or cataract formation is increased in diabetic patients;
- Contact your doctor if you experience blurred vision or other visual disturbances;

- If you have increased pressure in your eye(s). You should have your eye pressure checked regularly while using MAXITROL.
- if you are using other antibiotic treatment, including oral, with MAXITROL, ask your doctor for advice;
- if you use MAXITROL for a long period of time, you may become more susceptible to eye infections, have increased pressure in your eye(s) or develop cataracts;
- 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;
- Signs and symptoms of adrenal suppression include fatigue; light-headedness upon standing or difficulty standing, muscle weakness, fever, weight loss, anxiety, nausea, vomiting, diarrhoea, headache, sweating, changes in mood or personality, and joint and muscle pains.
- If you wear contact lenses:

  Wearing contact lenses (hard or soft) is not recommended during treatment of an eye inflammation or infection.

Other medicines and MAXITROL

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- if you are using topical NSAIDs (medicines used to treat used page to treat inflammation; mild to moderate pain; and fever). If you use topical steroids and topical NSAIDs together, it may increase corneal healing problems.
- if you are using ritonavir or cobicistat (medicines used to treat HIV/AIDS), as this may increase the amount of dexamethasone in the blood.

Pregnancy and breastfeeding and fertility

You should not use MAXITROL if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using MAXITROL.

Driving and using machinery

Temporarily blurred vision or other visual disturbances with use of MAXITROL may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

It is not always possible to predict to what extent MAXITROL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MAXITROL affects them.

MAXITROL® Ophthalmic suspension contains benzalkonium chloride

- 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.

MAXITROL® Ophthalmic ointment contains methylparahydroxybenzoate, propylparahydroxybenzoate and lanolin.

- This product contains methylparahydroxybenzoate and propylparahydroxybenzoate which may cause allergic reactions.
- This product contains lanolin which may cause local skin reactions.

3. How to use MAXITROL

Do not share medicines prescribed for you with any other person.

Always use MAXITROL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

MAXITROL® Ophthalmic Suspension:

- Instil one to two drops topically in the conjunctival sac(s) four to six times daily.
- Dosage may be reduced after three to four days when satisfactory improvement has been obtained.
- SHAKE BOTTLE WELL BEFORE USE.

MAXITROL® Ophthalmic Ointment:

- Apply a small amount of ophthalmic ointment into the conjunctival sac(s) three to four times daily.

- When favourable response is observed dosage may be reduced gradually to once a day application for several days.
- Your doctor will tell you how long your treatment with MAXITROL will last.
- If you have the impression that the effect of MAXITROL is too strong or too weak, tell your doctor or pharmacist.

If you use more MAXITROL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of MAXITROL

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

MAXITROL can have side effects.

Not all side effects reported for MAXITROL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MAXITROL, please consult your healthcare professional for advice.

If any of the following happens, stop using MAXITROL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- Stevens-Johnson syndrome (a serious disorder of the skin and mucous membranes. It's usually a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MAXITROL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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)*;
- Corneal ulcer.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported but the frequency is unknown:

- Vision blurred;
- photophobia (sensitivity to light);
- mydriasis (increase in pupil size);
- eyelid ptosis (drooping of eyelid);
- eye pain, eye swelling;
- foreign body sensation in eyes;
- ocular hyperaemia (eye redness);
- lacrimation increased (increased tear production);
- headache.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/. By reporting side effects, you can help provide more information on the safety of MAXITROL.

5. How to store MAXITROL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not use after 28 days of opening.
- Store in the original package / container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MAXITROL contains:

The active substances are:

MAXITROL® Ophthalmic Suspension

Each 1,0 mL contains:

Polymyxin B sulphate equal to 6000 international units polymyxin B base, neomycin sulphate equal to 3500 international units neomycin base and dexamethasone 1,0 mg.

MAXITROL® Ophthalmic Ointment

Each 1,0 g contains:

Polymyxin B sulphate equal to 6000 international units polymyxin B base, neomycin sulphate equal to 3500 international units neomycin base and dexamethasone 1,0 mg.

The other ingredients are*:*

MAXITROL® Ophthalmic Suspension:

Polysorbate 20

Sodium chloride

Hydrochloric acid

and/or Sodium hydroxide

Hydroxypropylmethylcellulose

Benzalkonium chloride

Purified water

MAXITROL® Ophthalmic Ointment:

Anhydrous liquid lanolin

Methyl paraben, Propyl paraben

White petrolatum

What MAXITROL looks like and contents of the pack

What MAXITROL looks like:

MAXITROL® Ophthalmic Suspension: White to pale yellow, opaque suspension**.**

MAXITROL® Ophthalmic Ointment: A greasy, translucent to opaque and white to light yellow, homogeneous ointment, free of lumps.

Contents of the pack:

MAXITROL® Ophthalmic Suspension: Low density polyethylene bottle containing 5 mL.

MAXITROL® Ophthalmic Ointment: Ophthalmic ointment tube containing 3,5 g.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Jukskei View

Waterfall City

Johannesburg

South Africa

2090

This leaflet was last revised in

Date of revision of text: 25 May 2022

Registration number

MAXITROL® Ophthalmic Suspension: H.1145 (Act 101/1965)

MAXITROL® Ophthalmic Ointment: H.1158 (Act 101/1965)

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website

Manufacturer

MAXITROL® Ophthalmic Ointment	MAXITROL® Ophthalmic Suspension
Siegfried El Masnou S.A., Camil Fabra 58, El Masnou, Barcelona S.A. Alcon-Couvreur N.V., Rijksweg 14, Puurs	S.A. Alcon-Couvreur N.V., Rijksweg 14, Puurs