TERRAMYCIN® EYE OINTMENT

Oxytetracycline/Polymyxin B (5 mg / 10,000 units per gram)

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What TERRAMYCIN is used for

TERRAMYCIN is used in the treatment of superficial eye infections.

How TERRAMYCIN works

TERRAMYCIN contains two different antibiotics, oxytetracycline and polymyxin B.

Oxytetracycline belongs to a group of medicines called tetracycline antibiotics.

The combination of oxytetracycline and polymyxin B works by killing or stopping the growth of bacteria causing your infection.

Before you use TERRAMYCIN

- *When you must not use it*

DO NOT use TERRAMYCIN if you have ever had an allergic reaction to oxytetracycline, polymyxin B or any of the other the ingredients of the ointment.

Pregnancy and lactation

The safety of topical (applied to body surfaces) tetracyclines has not been established in pregnant women. You should use topical tetracyclines only after discussing the potential benefits to you and the potential risks to your unborn child with your doctor.

It is not known whether topically applied tetracyclines are distributed into breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the medicine to the mother. Ask your doctor or pharmacist for advice before using this medicine.

- *Before you start to use it*

Check with your doctor before you use this medicine.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

There are no known interactions between TERRAMYCIN and other medicines.

How to use TERRAMYCIN

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Apply a small amount (approximately 1 cm) of the ointment into the lower lid. If you have swollen eyelids, remove the scales and crusts before applying the medicine.

- *When to use it*

Use 4 to 6 times daily or as directed by your doctor or pharmacist.

- *How long to use it*

Continue until the infection is cleared and healing is complete or use TERRAMYCIN for as long as your doctor recommends.

Clearing of infection and healing may take from one day to several weeks depending on the nature and severity of the infection.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have applied too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

There are no known cases of overdosage reported.

While you are using it

- *Things you must do*

Tell all the doctors, dentists and pharmacists treating you that you are using TERRAMYCIN.

Tell your doctor immediately if you become pregnant while using this medication.

Inform your doctor if any new infections appear during treatment with TERRAMYCIN because oxytetracycline may result in overgrowth of other infections, including fungi.

Avoid contamination of the tip of the tube when applying the ointment.

- *Things you must not do*

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give TERRAMYCIN to anyone else, even if they have the same symptoms or condition as you.

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- *Things to be careful of*

Driving and using machines

Oxytetracycline topical preparations are not likely to affect your ability to drive or use machines or tools.

The direct application of TERRAMYCIN ointment in the eye may reduce the sharpness of vision for a period of time.

Side effects

Like all medicines, TERRAMYCIN can cause side effects, although not everybody gets them.

Check with your doctor or pharmacist immediately if any of the following occur:

- Allergic reactions
- Burning sensation
- Overproduction of tears
- Contact dermatitis (red, sore or inflamed skin after direct contact with the medicine)
- Dark spot (skin hyperpigmentation)
- Eye pain
- A feeling of grittiness or having something in the eye
- It is known that tetracyclines when given as tablets during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discolouration of the teeth as well as underdeveloped tooth enamel and skeleton. Although these effects are unlikely following topical application of tetracyclines because of the low doses used, the possibility that these effects could occur should be considered.
- Similar side effects as tetracycline-class products, e.g., recurring rash (fixed eruption)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TERRAMYCIN

- *Storage*

Keep out of the reach and sight of children.

Store below 30° C.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

TERRAMYCIN is a smooth, light yellow homogenous ointment, free from foreign matter, available in aluminium tube of 3.5 g.

- *Ingredients*
  - Active ingredients
    Oxytetracycline hydrochloride and polymyxin B sulfate
  - Inactive ingredients
    Mineral oil, white petrolatum

- *MAL number*

Product Name	Registration Number
Terramycin Ophthalmic Ointment	MAL19970639ASZ

Manufacturer

PT Pfizer Indonesia
Jakarta, Indonesia

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11
Wisma Averis, Tower 2
Avenue 5, Bangsar South
No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

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