

## Tetracycline ointment

This information is a summary only. It does not contain all information about this medicine. If you would like more information about the medicine you are taking, check with your doctor or other health care provider. No rights can be derived from the information provided in this medicine leaflet.

### TETRACYCLINE 10 mg/g eye ointment

Tetracycline hydrochloride

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- 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.

#### What is in this leaflet

1. What Tetracycline is and what it is used for
2. What you need to know before you use Tetracycline
3. How to use Tetracycline
4. Possible side effects
5. How to store Tetracycline

#### 1. What Tetracycline is and what it is used for

Tetracycline belongs to a group of medicines, called tetracycline antibiotics. These are active against a large number of microorganisms causing different infections and inflammations. Tetracycline activity is realised through slowing down or stopping the development of microorganisms. Tetracycline is active in case of bacterial infections only. It is indicated for the treatment of superficial eye infections, caused by tetracycline-susceptible microorganisms:

Blepharitis (inflammation of the eyelids), inflammation of the ocular surface (conjunctivitis), keratitis (inflammation of the cornea), dacryocystitis (inflammation of the tear sac), sty, trachoma (a serious infectious eye disease, caused by chlamydiae);

It is also used for:

- Pre- and postoperative prevention of inflammation in eye surgery;
- Prevention of neonatal conjunctivitis (a type of infection caused by gonococci).

#### 2. What you need to know before you use Tetracycline

##### Do not use Tetracycline

if you are allergic (hypersensitive) to tetracycline or any of the other ingredients of this medicine (listed in section 6).

if you are allergic (hypersensitive) to any other medicine of the group of tetracycline antibiotics.

##### Warnings and precautions

Talk to your doctor before using Tetracycline .

If you experience itching and swelling of the eyelids, reddening of the eye, swelling of the face or throat, skin rash or any other symptom of an allergic reaction, stop using Tetracycline and contact your attending physician.

You may become more sensitive to sunlight while using Tetracycline . Avoid exposure to intensive sunlight during this period.

Prolonged use of Tetracycline , as well as other antibiotic products, may result in development of a superinfection with bacteria or fungi, non-susceptible to the antibiotic. Apply Tetracycline as long as prescribed.

If you are pregnant, the risk for the baby should be evaluated very carefully during the treatment with Tetracycline .

The simultaneous administration of Tetracycline with corticosteroids for ocular use (dexamethasone, prednisolone or hydrocortisone) is not recommended, since some unfavourable symptoms may be masked.

You should not wear contact lenses in case of available eye infection.

#### Other medicines and Tetracycline

Tell your doctor if you are taking/using, have recently taken/used or might take/use any other medicines.

Tetracycline may affect the activity of other topical antibiotics (penicillin, cephalosporins, aminoglycosides), for which, they should not be applied simultaneously.

The simultaneous administration of Tetracycline with corticosteroids for ocular use (dexamethasone, prednisolone or hydrocortisone) is not recommended, since some unfavourable symptoms may be masked.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

If you are pregnant, making attempts to get pregnant or breast-feeding at present, Tetracycline should be administered with caution and by your attending physician's prescription only, since it may affect the skeletal development, bone growth and teeth of the baby.

#### Driving and using machines

As with all products for ocular use, transient blurring of or other disturbances may affect the ability to drive and use machines. You should wait until your clears, before you start operating machines or driving.

#### Tetracycline contains lanoline, propyl parahydroxybenzoate and methyl parahydroxybenzoate

In its composition, Tetracycline eye ointment includes lanoline, which may cause a local allergic reaction (for example, contact dermatitis).

In its composition, Tetracycline eye ointment includes propyl parahydroxybenzoate and methyl parahydroxybenzoate, which may cause allergic reactions (possibly of a delayed type) and, very rarely, bronchospasm.

#### 3. How to use Tetracycline

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

Adults and children: depending on the severity of condition, a strip of the eye ointment with length of 1 – 1.5 cm is inserted into the conjunctival fold of the lower eyelid 3 - 4 times daily and in more severe cases, up to 6 times daily.

The dosage and duration of the treatment are determined by the attending physician, as the usual duration of treatment is 5 - 7 days.

The treatment should continue for 2 -3 days after symptom abatement.

In more severe eye infections, acute or chronic trachoma, the course of treatment may continue for 1 - 2 months, as the topical application can be combined with oral antibiotic therapy.

For prevention of neonatal conjunctivitis, a strip of the eye ointment with length of 0.5 – 1 cm is inserted into the conjunctival folds of the lower eyelids of both eyes within 1 hour post delivery.

A new tube should be opened for each newborn baby!

During simultaneous application with another product for ocular use, the interval between the applications of the two products should be at least 10 minutes, as the eye ointment should be applied last.

Keeping hygiene during the application of the eye ointment and avoiding the contact between the tip of the tube and the eye or surrounding objects are of

importance, since the tip may be contaminated, thus leading to development of eye infection with serious sequels for the eye, even to loss of .

Always wash your hands before using the tube!

If you think that your tube is contaminated, contact your doctor before continuing the application of this eye ointment.

### Instructions for use

1. Before you start using the tube, make sure that the protective strip between the cap and the tube is not broken. Wash your hands and unscrew the cap.
  2. Hold the tube between your thumb and index finger, as close as possible to the eyelid, without touching it.
  3. Tilt your head slightly forward and pull the lower eyelid away from your eye to form a pouch between the eyelid and the eye. The strip of the eye ointment will fall just into this place.
  4. Pay attention not to touch the tip of the tube to the eye, eyelid or adjacent surfaces. Squeeze carefully a strip of the ointment with length of about 1-1.5 cm, in a way to fall into the formed pouch of the lower eyelid.
  5. After you have applied Tetracycline, close slightly the eyelid for 1-2 minutes and rotate the eyeball in all directions, to enable the spread of the ointment on the entire ocular surface.
  6. Using a clean tissue, remove the excessive amount of the ointment from the eyelid or eyelashes. Using another clean tissue, wipe the tip of the tube and close it tightly with the cap.
  7. If it is necessary to apply the eye ointment in the other eye, repeat all previously described steps for the other eye.
- Use this tube of Tetracycline for your eyes only!

### If you use more Tetracycline than you should

Tetracycline can be rinsed out from the eye/eyes with tempered water.

### If you forget to use Tetracycline

Apply the dose as soon as you remember. If it is almost the time for your next dose, continue according to your usual regimen. Do not apply a double dose to make up for a forgotten application.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

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

There are reports of side effects, possibly related with the application of tetracycline for ocular use, but these are mild and rapidly alleviating after treatment discontinuation.

#### *Eye disorders*

Blurred, sensation of burning, stinging, itching in the eye or eyelid, reddening of the conjunctiva, swelling of the eyelid, lacrimation (excessive tear discharge) and pain.

#### *Immune system disorders*

Local allergic reactions – inflammation and irritation of the skin, rash, itching, photodermatitis (increased sensitivity to sunlight and UV rays).

General allergic reactions – rash, itching/swelling (of the face, tongue, throat), vertigo, shortness of breath.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

### 5. How to store Tetracycline

Keep this medicine out of the sight and reach of children.

Store below 25°C.

In-use period after first opening of the pack: 28 days at a temperature below 25°C, in a tightly closed tube.

Dispose of the tube in 28 days after opening, to avoid eventual infections and contaminations.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any change in the appearance or consistency of the eye ointment.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.