

## **Package leaflet: Information for the user**

### **TETRACYCLINE VISION 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 Vision is and what it is used for
2. What you need to know before you use Tetracycline Vision
3. How to use Tetracycline Vision
4. Possible side effects
5. How to store Tetracycline Vision
6. Contents of the pack and other information

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

Tetracycline Vision 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 Vision 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 Vision**

### **Do not use Tetracycline Vision**

- 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 Vision.

- 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 Vision and contact your attending physician.
- You may become more sensitive to sunlight while using Tetracycline Vision. Avoid exposure to intensive sunlight during this period.
- Prolonged use of Tetracycline Vision, as well as other antibiotic products, may result in development of a superinfection with bacteria or fungi, non-susceptible to the antibiotic. Apply Tetracycline Vision as long as prescribed.
- If you are pregnant, the risk for the baby should be evaluated very carefully during the treatment with Tetracycline Vision.

- The simultaneous administration of Tetracycline Vision 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 Vision**

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

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

The simultaneous administration of Tetracycline Vision 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 Vision 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 vision or other disturbances may affect the ability to drive and use machines. You should wait until your vision clears, before you start operating machines or driving.

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

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

In its composition, Tetracycline Vision 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 Vision**

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

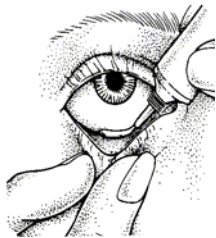
importance, since the tip may be contaminated, thus leading to development of eye infection with serious sequels for the eye, even to loss of vision.

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 Vision, 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 Vision for your eyes only!

### **If you use more Tetracycline Vision than you should**

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

### **If you forget to use Tetracycline Vision**

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 Vision 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 vision, 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 Vision**

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.

## **6. Contents of the pack and other information**

### **What Tetracycline Vision contains**

- The active substance is tetracycline hydrochloride of 10 mg/g.
- The other ingredients are methyl parahydroxybenzoate; propyl parahydroxybenzoate; paraffin, liquid; paraffin, hard; lanoline; paraffin, white soft (*Vaselineum album*).

### **What Tetracycline Vision looks like and contents of the pack**

Tetracycline Vision 10 mg/g eye ointment is a yellow to dark yellow ointment with homogenous consistency, no agglomerates and air bubbles.

Tetracycline Vision 10 mg/g eye ointment is packed in sterile, aluminium cannula-fitted, lacquered tubes with a latex ring at the lower end, closed with a plastic screw cap fitted with a “tamper-evident” ring.

Quantity in one tube: 2.5 g; 3.5 g; 5 g

1 (one) tube with a patient leaflet is inserted in a cardboard carton.

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