

PACKAGE LEAFLET: Information for the user

TETRACIKLINE

Ointment – 3%

TETRA

Eye ointment – 1%

(Tetracycline hydrochloride)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects worsens or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Tetracikline or Tetra is and what it is used for
2. Before you use Tetracikline or Tetra
3. How to use Tetracikline or Tetra
4. Possible side effects
5. How to store Tetracikline or Tetra
6. Further information

1. WHAT TETRACIKLINE OR TETRA IS AND WHAT IT IS USED FOR

Tetracikline or Tetra contains the active substance tetracycline hydrochloride.

Tetracycline is a semi-synthetic derivative of chlortetracycline. It has bacteriostatic action as a result of reversible inhibition of microbial ribosome and protein synthesis. Locally, tetracycline is effective in treating minor skin infections caused by streptococci, staphylococci and other sensitive bacteria.

Tetracycline acts good on the cause of trachoma (*Chlamydia trachomatis*).

Tetracikline 3%, 15 g ointment is used in:

- infectious ulcerations of derma;
- acne vulgaris;
- bacterial infections of the skin and soft tissue (treatment and prophylaxis);
- scratches, wounds or bites from dogs and cats, or insect bites for the prevention of development of infection.

Tetra 1%, 5 g eye ointment is used:

- to treat superficial bacterial infections of the eye's cornea and eye conjunctivitis;
- to prevent ophthalmia neonatorum;
- to treat trachoma.

After using tetracycline for a long period of time, resistance to microorganisms may appear.

2. BEFORE YOU USE TETRACIKLINE OR TETRA

Do not use Tetracikline or Tetra if:

- you are sensitive (allergic) to tetracycline or to any other ingredients of the eye ointment and dermatologic ointment (hypersensitivity reactions are more frequent in asthmatic patients);
- you are pregnant or breastfeeding.

Tetra eye ointment is not recommended to be combined with ophthalmic corticosteroid therapy. This combination may hide the clinical signs of bacterial, viral and fungal infections.

Take special care with Tetracikline or Tetra

Ask your doctor before using Tetracikline or Tetra.

- Consult with your doctor before using the eye ointment and dermatologic ointment in children.
- Dermatologic ointment should not be applied in the eye.
- It is allowed to use Tetracikline dermatologic ointment in children older than 8 years old.
- Use for a long period of time and in large amounts is contraindicated.

- The use of antibiotics can cause the development of pathogenic organisms, so the patient should be monitored with caution. If during treatment, a new infection appears, the appropriate measures should be taken.
- The 3%, 15 g ointment, as dermatologic ointment, can not be used in nasal or oral mucosa or in the eye.
- The 1%, 5 g eye ointment is used only in the eye and not in oral or nasal mucosa.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Tetracikline or Tetra. Please tell your doctor or pharmacist if you are taking / using or have recently taken / used any other medicines, including those obtained without a prescription.

It is especially important that your doctor knows that you are being treated with:

- resorcinol;
- benzoyl peroxide;
- salicylic acid.

All of these drugs increase the irritating effect on skin.

Using Tetracikline or Tetra with food or drinks

Personal hygiene rules should be taken in consideration. Food and drinks should not be consumed with hands where tetracycline dermatologic ointment is applied.

In terms of a perfect personal hygiene, there is no effect on food intake and drinks consumption during treatment with dermatological and ophthalmic ointment (local application).

Pregnancy

This drug can be used during pregnancy only when the need for it outweighs the risk to which the fetus and mother are exposed. The treatment of pregnant women with tetracycline harms the teeth continuously.

Breastfeeding

Treatment with tetracycline during breastfeeding is contraindicated, because even though tetracycline is administered locally, it accumulates in breast milk and is excreted with milk. For

this reason, mothers who are breast-feeding should not use tetracycline, except in cases where the need for it outweighs the risk to which the child is exposed. Use of tetracycline during breast-feeding may cause teeth discoloration in children.

Ask your doctor or pharmacist for advice before using this drug.

Driving and using machines

Tetracikline 3% ointment has no effect on the ability to drive and use machines.

Like any other drug that is applied in the eye, Tetra 1% eye ointment also can cause temporary blurred vision, which can affect the ability to drive or use machines. If blurred vision appears, you should wait until total clear vision has returned before driving or using machines.

Important information about some of the ingredients of Tetracikline or Tetra

Tetracikline 3% ointment contains methylhydroxybenzoate (nipagin) and propylhydroxybenzoate (nipasol), that may cause allergic reactions (possibly delayed).

Tetra 1% eye ointment contains methylhydroxybenzoate (nipagin), that may cause allergic reactions (possibly delayed).

3. HOW TO USE TETRACIKLINE OR TETRA

Always use Tetracikline or Tetra exactly as your doctor has told you. Talk to your doctor or pharmacist if you are not sure.

Tetracikline 3%, 15 g ointment

After cleaning the skin, it is applied locally in a thin layer twice a day. The ointment is easily spread with the finger until it is not visible. In bacterial skin infections, treatment for up to 1 week is needed while in acne up to 3 weeks (in mild to moderate forms, local medication is enough, while in severe forms the local medication can be combined with tablets taken orally, 1.5 g / day divided into 3 parts taken 1 hour before or 2 hours after meals).

Tetra 1%, 5 g eye ointment

- *For the treatment of bacterial infections and trachoma:*

the eye ointment (1%) is applied about 1 cm in conjunctiva, every 2-4 hours.

- *For the treatment of ophthalmia neonatorum:*

one single dose of ointment is applied (1 cm).

The initiation of treatment and the repeated treatment should be done only after a careful examination of the patient by the specialist through the control with biomicroscope, etc.

If the treatment duration is over 10 days, the intraocular pressure should be checked.

For the administration of Tetra 1% eye ointment, follow the given instructions:

- Wash your hands thoroughly.
- Avoid touching the tip of the tube with the eyelash, conjunctiva, skin, fingers or other surfaces.
- Do not touch the tip of the tube.
- Look upward.
- Pull down the lower lid of your eye to form a pocket.
- Put the tip of the tube close to the pocket, but without touching it.
- Put the right quantity in the pocket.
- Close your eye for two minutes.
- Using the same tube in more than one patient, can cause the infection spreading.

The preparation should be kept closed while it is not used, because when proper care is not shown, it may be contaminated and cause eye infections that may be a reason for serious damage of the eye and vision.

If you use more Tetracikline or Tetra than you should

Tetracycline is well absorbed from the skin when applied locally, for this reason care must be taken not to use large quantities because it may cause skin irritation and burn.

If you use more Tetracikline or Tetra than you should, or if the children take it accidentally, please contact your doctor, the hospital, or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to use Tetracikline or Tetra

If you forget the application of one dose (or more doses), apply the next dose in its usual time.

Do not apply a double dose (or more) at the same time.

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

4. POSSIBLE SIDE EFFECTS

Like any other drug, Tetracikline or Tetra may cause side effects, although not everybody gets them.

Most of the side effects are dose related and disappear with dose reduction or treatment interruption. Some of the side effects occur at the beginning of the treatment or disappear spontaneously during the treatment.

Some possible side effects of Tetracikline 3% ointment are:

- coloring of the skin at the site of use, but spots cleaned by washing;
- fluorescence of treated areas because of ultraviolet rays;
- irritation, itching, redness, burning or oedema at the site of application;
- very rarely dermatitis;
- in patients with renal insufficiency, if local treatment is supplemented by taking complete oral dose, liver damage may occur.

Tetra 1%, 5 g eye ointment:

- irritation, itching and burning of the eyelids;
- visual disturbances may also be caused.

5. HOW TO STORE TETRACIKLINE OR TETRA

Do not use the drug after the expiry date which is stated on the package.

Keep in the original package to protect it from light.

To be stored in a cool place, below 25°C.

Keep out of the reach and sight of children.

6. FURTHER INFORMATION

What Tetracikline 3%, 15 g ointment contains

The **active substance** is tetracycline hydrochloride.

1 g ointment contains 30 mg tetracycline hydrochloride.

Other ingredients: white soft paraffin, light liquid paraffin, colloidal anhydrous silica, methylhydroxybenzoate (nipagin), propylhydroxybenzoate (nipasol).

What Tetra 1%, 5 g eye ointment contains

The **active substance** is tetracycline hydrochloride.

1 g eye ointment contains 10 mg tetracycline hydrochloride.

Other ingredients: white soft paraffin, light liquid paraffin, methylhydroxybenzoate (nipagin).

Contents of the pack

Tetracikline 3% ointment: box with one tube of 15 g.

Tetra 1% eye ointment: box with one sterile tube of 5 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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