PACKAGE LEAFLET: Information for the patient

OKSITETRACIKLINE

Tablets – 250 mg

(Oxytetracycline)

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

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medication 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. WHAT OKSITETRACIKLINE IS AND WHAT IT IS USED FOR

Oxytetracycline is an antibiotic that belongs to the group of tetracyclines. Like other tetracyclines (tetracycline, chlortetracycline), it is a bacteriostatic antibiotic with broad spectrum and is used for the treatment of a large number of infections caused by susceptible microorganisms. Oxytetracycline acts against chlamydia, mycoplasma, rickettsia and spirochete, and against many pathogenic gram - positive and gram - negative bacteria and some protozoa.

In general, fungi, yeasts and viruses are resistant to oxytetracycline. Most tetracyclines are incompletely absorbed from the gastrointestinal tract (about 60 to 80% of a used dose). The rate of absorption is reduced by the presence of bivalent and trivalent metal ions and to a certain degree also by the presence of milk and its products, with which tetracyclines form stable insoluble complexes. Peak plasma concentrations occur 1 to 3 hours after oral use.
Tetracyclines are bound to plasma proteins to varying degrees, but reported values differ considerably, ranging from 20 to 40% for oxytetracycline, 20 to 65% for tetracycline, and about 45% for chlortetracycline. They are widely distributed throughout the body tissues and fluids.
Concentrations in cerebrospinal fluid are relatively low, but may be raised if the meninges are inflamed, and small amounts appear in saliva, in the fluids of the eye and lung.
Tetracyclines are excreted in breast milk, where concentrations may reach 60% or more of those in plasma. They diffuse across the placenta and appear in the fetal circulation. Tetracyclines are retained at sites of new bone formation and recent calcification and in developing teeth. Half-life of oxytetracycline is 9 hours. The tetracyclines are excreted in the urine and in the faeces.

Oksitetracikline is used in:
bacterial pneumonia and bronchopneumonia, acute and reactivated infections of urinary tract, surgical infections, acute and subacute infections of the intestinal tract, acute and subacute endocarditis, epidemic cerebrospinal meningitis and purulent meningitis in general, brucellosis, rickettsiosis, otorhinolaryngologic infections (amygdalitis, otitis, sinusitis, mastoiditis), ophthalmologic infections (conjunctivitis, blepharitis, trachoma), gynecological infections (metritis, adnexitis), skin infections and soft tissue (furunculosis, impetigo, acne vulgaris), syphilis.

2. BEFORE YOU TAKE OKSITETRACIKLINE

Do not take Oksitetracikline if:

- you are hypersensitive (allergic) to oxytetracycline (or tetracyclines) or to any of the excipients of Oksitetracikline;
- you have severe impairment of renal function;
- you are pregnant;
- you are under 12 years of age;

- you suffer from systemic lupus erythematosus;
- you suffer from porphyria.

Warnings and precautions

Ask your doctor or pharmacist before taking Oksitetracikline.

Oxytetracycline should be used with caution in patients with impaired liver function and impaired renal function (should be avoided when the impairment is severe).

It should be used with caution in patients with myasthenia gravis.

Patients who use tetracyclines should be warned of the risk during exposure to the sun because of photosensibility. It should be avoided during breastfeeding.

Oxytetracycline use may cause permanent discoloration of the teeth during teeth development period in children under 12 years of age.

Antacids inhibit oxytetracycline absorption, the same effect also exerts milk and its products, for this reason they should not be used simultaneously.

Taking other medicines

Concomitant treatment with other medicines can affect or be affected by Oksitetracikline.

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Remember to inform your doctor about the treatment with Oksitetracikline if you take any other drug during treatment.

The main interactions are listed below:

- antacids and bi- and trivalent cations inhibit oxytetracycline absorption;
- oxytetracycline may increase digoxin serum levels;
- oxytetracycline may reduce the effect of oral contraceptives;
- tetracycline may interfere with the bactericidal action of penicillin;
- milk and its products inhibit oxytetracycline absorption;
- sucralfate reduces tetracycline absorption;
- tetracyclines increase the anticoagulant effect of warfarin and other anticoagulants;
- tetracyclines increase photosensitivity caused by griseofulvine, phenothiazines, sulfonamides, sulphonylureas, thiazide diuretics, analogues of vitamin A.

Pregnancy

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

Oksitetracikline use is not recommended during pregnancy.

Breastfeeding

If you are breastfeeding, ask your doctor or pharmacist for advice before taking this medication.

Oxytetracycline passes into breast milk and therefore should be avoided during breastfeeding.

Driving and using machines

Oxytetracycline may cause vision disorders, which may affect the patient's ability to drive or operate machinery.

3. HOW TO TAKE OKSITETRACIKLINE

Always take Oksitetracikline exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you feel that the effects of Oksitetracikline are too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with at least half glass of water.

The usual dose is 1 - 2 g, which is given in 4 equal doses (every 6 hours), depending on the gravity of the infection. Treatment should be continued at least 24 - 48 hours after symptoms and fever are gone. Oxytetracycline, like all tetracyclines, should be taken 1 hour before or 2 hours after meals, with plenty of liquid.

Recommended dosage in specific infections:

Acne vulgaris and aggravated rosacea: 250-500 mg per day as a single dose or in divided doses;

Brucellosis: 500 mg, 4 times a day, combined with streptomycin;

Sexually transmitted diseases: 500 mg, 4 times a day, for 7 days, while in the following infections are used the following doses: uncomplicated urethral, endocervical or rectal gonococcal infections, caused by *Chlamydia trachomatis*; non-gonococcal urethritis caused by *Ureoplasma urealyticum*; epididimo - acute orchitis caused by *Chlamydia trachomatis* or *Neisseria gonorrhoeae*: 500 mg, 4 times a day, for 10 days;

Primary or secondary syphilis: 500 mg, 4 times a day, for 15 days.
However doses may need to be increased or to decrease. Your doctor will advise you accordingly.

If you take more Oksitetracikline

If you take more Oksitetracikline 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 take Oksitetracikline

If you forget to take one dose (or more than one dose), take the next dose in its usual time. Do not take a double dose (or higher) to make up a forgotten dose(s).
If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Oksitetracikline may cause side effects, although not everybody gets them. Sometimes they are serious, sometimes they are not. Do not get alarmed by this list of possible side effects. You may not get any of them.
Most frequent adverse effects are:
nausea, vomiting, diarrhea, erythema (treatment should be stopped), headaches and vision disorders (may indicate the beginning of intracranial pressure), dry mouth, discoloration of the tongue, stomatitis, pseudomembranous collitis, photosensibilisation.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE OKSITETRACIKLINE

Keep this medicine out of the sight and reach of children.
Do not use Oksitetracikline after the expiry date which is stated on the pack.
Do not store above 25°C!
Keep in the original package to protect it from light.

6. FURTHER INFORMATION

What Oksitetracikline tablets contain

The **active substance** is oxytetracycline.

Each tablet contains 250 mg oxytetracycline.

The **excipients** are: microcrystalline cellulose, sodium starch glycolate, povidone K-30, hydrogenated vegetable oil, silica, colloidal anhydrous and magnesium stearate.

Contents of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in September 2023.