

PACKAGE LEAFLET: Information for the patient

TETRACYCLINE

Capsules – 250 mg

(Tetracycline hydrochloride)

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 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. Before you take Tetracycline
3. How to take Tetracycline
4. Possible side effects
5. How to store Tetracycline
6. Other information

1. WHAT TETRACYCLINE IS AND WHAT IT IS USED FOR

Tetracycline contains tetracycline hydrochloride as active substance, which is an antibiotic and it is useful in treating a wide range of bacteria which cause infections, such as:

- respiratory tract infections such as pneumonia and bronchitis;
- urinary tract infections;
- post - surgery infections such as osteomyelitis, soft tissue infections;
- intestine infections: infective diarrhoea, acute and subacute syndrome of diarrhoea;
- heart infections, acute and subacute;
- brain infections (epidemic cerebrospinal meningitis and purulent meningitis);

- brucellosis (a bacterial infection which generally manifests with fever, sweating, weight loss, headache, muscle pain);
- rickettsiosis (an infection that usually occurs with fever, headache, general discomfort, inflammation of small blood vessels and which is often associated with skin eruption);
- ear, nose, throat infections (otitis, sinusitis, tonsillitis, mastoiditis);
- eye infections, for example: eyelid infections (blepharitis); conjunctivitis, the infections of the membrane that covers the eye and the inner part of the eyelid; infections of the cornea, the transparent front part of the eye, caused by particular bacteria (trachoma);
- infections of the female reproductive system, for example: infections of the uterus (metritis, cervicitis), of the ovaries and tubes (adnexitis), and of the vagina (vulvovaginitis);
- bacterial infections of the skin: localized (furunculosis) or diffused (impetigo: infections that occur with blisters with pus on the skin).

Talk to your doctor if you do not feel better or if you feel worse.

2. BEFORE YOU TAKE TETRACYCLINE

Do not take Tetracycline if:

- you are hypersensitive to tetracycline hydrochloride, other similar antibiotics or to any of the other ingredients of this medicine;
- you have had kidney or liver problems for a long time or severe kidney disease;
- you have systemic lupus erythematosus (SLE), a condition characterised by rash (especially on the face), hair loss, fever, malaise and joint pain;
- the patient is under 12 years of age;
- you are pregnant or breast-feeding (see sections “Pregnancy” and “Breast-feeding”).

Take special care with Tetracycline

Ask your doctor or pharmacist before taking Tetracycline.

Photosensitivity reactions may occur during treatment in hypersensitive persons so you should avoid direct exposure to natural sunlight or artificial light and discontinue therapy if you notice the first signs of skin discomfort.

Caution is required when administered to patients with myasthenia gravis as neuromuscular blockade may occur.

Exacerbation of SLE (systemic lupus erythematosus) may occur with the use of tetracyclines. Tetracyclines depress plasma prothrombin activity, therefore reduced dosages of concurrent anticoagulants may be required.

Special attention should be given to patients with renal impairment due to accumulation of tetracycline in the blood with possible liver damage.

The use of antibiotics may occasionally result in the overgrowth of non-susceptible organisms including *Candida*. Constant observation of the patients is essential. If a resistant organism appears, the antibiotic should be discontinued and appropriate therapy instituted.

Diarrhoea occurring during or after treatment with Tetracycline capsules may be a symptom of *Clostridium difficile* - associated disease (CDAD) which may range in severity from mild to life threatening disease. If CDAD is suspected or confirmed, Tetracycline capsules should be stopped immediately and appropriate therapy should be initiated without delay. Antiperistaltic drugs are contraindicated in this clinical situation.

Children

The use of tetracyclines during the period of teeth formation (in the second half of pregnancy, neonatal period and early childhood) can cause permanent tooth discolouration (yellow to brown).

Tetracycline is contraindicated in children under 12 years of age.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those without a prescription.

- *Penicillins*, antibiotics to treat bacterial infections, such as amoxicillin, flucloxacillin or phenoxyethylpenicillin: tetracyclines can reduce the effectiveness of penicillins.
- *Antacids* to treat indigestion or heartburn, or over the counter medicines or supplements containing aluminium, calcium, iron, magnesium, bismuth or zinc. These medicines should not be taken at the same time as the absorption of tetracycline may be reduced.
- *Anticoagulants*: tetracyclines enhance the anticoagulant effect of coumarins and phenindione.
- *Retinoids*: to treat eczema, acne or other skin conditions: possible increased risk of benign intracranial hypertension when tetracyclines given with retinoids.

- *Dairy products*: reduction of tetracycline absorption.
- *Hepatotoxic drugs*: drugs that damage your liver; in such case great caution is required in case of concomitant administration with tetracycline.

Taking Tetracycline with food and drinks

Do not take Tetracycline at the same time with milk, dairy products or food, as they can reduce the amount of medicine absorbed by your body, making it less effective in fighting infection.

To avoid the esophageal irritation, take the product with an adequate amount of water.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medication. Tetracycline should be avoided during pregnancy

Breastfeeding

It is not recommended to use this medicine during breastfeeding unless your doctor considers it essential, as it may affect the development of your baby.

Driving and using machines

There are no data showing that tetracycline affects the ability to drive and use machines.

3. HOW TO TAKE TETRACYCLINE

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

Adults and children over 12 years

The recommended dose is 1 capsule 250 mg every 6 hours, one hour before or two hours after meals. In case of severe infections your doctor may increase your dosage to 500 mg (2 capsules) every 6 hours.

Specific infections:

Skin infections: 1 - 2 capsules (250 - 500 mg) daily either as a single dose or in divided doses for three months.

Brucellosis: 2 capsules (500 mg) four times daily with streptomycin.

Sexually transmitted diseases: 2 capsules (500 mg) four times daily for 7 to 30 days depending on your condition.

To avoid the esophageal irritation, take the product with an adequate amount of water.

Children under 12 years of age

Tetracycline is not recommended in children younger than 12 years of age as it can cause permanent discolouration of tooth enamel and affect bone development.

Elderly

Usual adult dose. Tetracycline should be used with caution in the treatment of elderly patients.

If you take more Tetracycline than you should

If you take more Tetracycline than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital, or call the emergency to get an opinion on the risk and advice on the actions that should be taken.

If you forget to take Tetracycline

Do not take a double dose to make up for a forgotten dose.

If you forget to take Tetracycline, take your dose as soon as you remember unless it is time to take the next dose. Use doses at the right time.

If you stop taking Tetracycline

You should continue taking Tetracycline for as long as your doctor has told you to, even if you start to feel better. If you stop before finishing the prescribed course of treatment your infection may still be present or may reappear.

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.

- Allergic reaction, the symptoms of which may include skin rash which may be itchy, swelling of your face, eyelids, lips, tongue or throat, sudden wheezing, chest pain or tightness, breathing difficulties, collapse.
- Increased pressure in the skull, which can cause severe headache, dizziness, 'ringing' in the ears, visual problems including blurred vision, 'blind spots', double vision.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), appearing initially as reddish target-like spots or circular patches often with central blisters. The rash may progress to widespread blistering or peeling of the skin. Additional signs include ulcers in the mouth, throat, nose or genitals, red swollen eyes (conjunctivitis) and flu-like symptoms.
- A decrease or loss of vision/eyesight.
- Severe or prolonged diarrhoea which may have blood or mucus in it, this may be a sign of serious bowel inflammation.

Tell your doctor if any of the following side effects occur:

Rare (affect less than 1 in 1,000 people)

- Inflammation of the liver (hepatitis), liver failure or yellowing of the skin or whites of the eyes (jaundice), changes in liver function (seen in blood tests).
- Increased levels of urea, phosphates or acid in the blood or changes in the numbers and types of your blood cells. If you notice increased bruising, bleeding, sore throats, infections, fever, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.
- Ulcers in the throat, difficulty swallowing.
- Problems with your kidneys, causing changes in your urine, tiredness, weakness, shortness of breath and swelling due to fluid retention.

Unknown frequency:

- Increased sensitivity to sunlight or artificial light (sun-beds or sun-lamps) causing itching,

stinging and burning of the skin. You should limit your exposure to natural sunlight, and avoid exposure to artificial light, where possible.

- Overgrowth of some resistant organisms causing infections, such as thrush, affecting the genitals or anus.
- Pseudomembranous colitis, the symptoms of which include watery diarrhoea, abdominal cramps and fever.
- Worsening of the inflammatory disease Systemic Lupus Erythematosus (SLE), which causes skin rashes, fever and joint pain.
- Increase in muscle weakness in patients suffering from myasthenia gravis, headache.
- Stomach upsets, feeling or being sick, diarrhoea, loss of appetite, discolouration of tooth enamel, inflammation of the pancreas (pancreatitis) causing discomfort or pain in the abdomen.
- Poor kidney function leading to changes in the need or frequency to pass water, swelling in the legs or ankles.
- Fatty liver, causing tiredness and discomfort in your upper abdomen.
- Discoloured thyroid tissue (no changes in thyroid function are known to occur).

If you get any side effects, talk to your doctor, or pharmacist. 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.

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

Do not store above 25°C.

6. OTHER INFORMATION

What Tetracycline 250 mg capsules contain

The active substance is tetracycline hydrochloride.

Each capsule contains 250 mg tetracycline hydrochloride.

The excipients are: pregelatinized starch, magnesium stearate, standard gelatin capsule.

Content of the pack

Carton box with 60 capsules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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