

PATIENT INFORMATION LEAFLET

TETRACYCLINE 250 MG COATED TABLETS

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Please 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 questions please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms 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.

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1. What Tetracycline Tablets are and what they are used for

Tetracycline is a broad-spectrum antibiotic, which is a substance with an anti-bacterial action. It may be used to treat a wide range of infections caused by bacteria and fungal organisms, these include:

- Respiratory Tract infections such as bronchitis, pneumonia or whooping cough.
- Urinary Tract infections.
- Sexually transmitted diseases such as chlamydia, gonorrhoea or syphilis.
- Skin infections such as acne.
- Infections of the eye such as conjunctivitis.
- Rickettsial such as Q fever and tick-borne fever (severe headache, rash, high fever).
- Other infections such as brucellosis (headache, sickness, fever, swollen lymph nodes), psittacosis (headache, nose bleeds, shivering, fever), plague (painful swelling of the lymph nodes), cholera (severe sickness and diarrhoea), leptospirosis (fever causing jaundice or meningitis), gas-gangrene and tetanus (lock jaw).

2. Before you take Tetracycline Tablets

Do not take Tetracycline Tablets and tell your doctor if:

- You are allergic to the tetracycline group of drugs or to any of the other ingredients contained in these tablets (listed in section 6). An allergic reaction may be recognised as a rash, itching, swollen face or lips, or shortness of breath.
- You are pregnant or breast-feeding (see 'Pregnancy and breast feeding' section below for further details).
- You are suffering from a severe liver or severe kidney complaint.
- You are suffering from Systemic Lupus Erythematosus (an immunological disorder affecting connective tissue and vessels of the skin, nervous system, heart, lungs, kidneys, joints and other organs).
- You are intending to give to a child under 12 years of age (since children under 12 should not be given this medicine).

Take special care with Tetracycline Tablets and tell your doctor if:

- You are sensitive to light (which is known as having 'photosensitivity').
- You suffer from myasthenia gravis (a condition characterised by unusual muscle weakness, difficulty chewing and swallowing and slurred speech).
- You are suffering from a liver or kidney complaint.

Taking / Using other medicines:

Please **tell** your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription. The following are some of the drugs with which Tetracycline Tablets may interact:

- Penicillins (a type of antibiotic, such as phenoxymethylpenicillin, to treat infections).
- Vitamin A.
- Retinoids such as acitretin, isotretinoin and tretinoin (to treat acne).
- Oral contraceptives ('The Pill') which is a type of birth-control. Tetracycline Tablets may make the oral contraceptive pill less effective. You should use additional contraceptive precautions whilst taking Tetracycline Tablets and for 7 days after stopping.
- Anticoagulants (drugs used to thin the blood).
- Diuretics (i.e. 'water tablets' such as furosemide, which decrease blood volume by increasing urine production).
- Kaolin-pectin and bismuth subsalicylate (to treat diarrhoea).
- Medicines to treat diabetes such as insulin, glibenclamide or gliclazide.
- Atovaquone (to treat pneumonia).
- Iron, calcium, aluminium, magnesium, bismuth or zinc containing medicines/preparations (such as mineral supplements or antacids).
- Sucralfate (to treat ulcers)
- Lithium (to treat bipolar disorder, depression)
- Digoxin (to treat an uneven heartbeat (arrhythmia))
- Methotrexate (used in rheumatoid arthritis)
- Strontium ranelate (for osteoporosis)
- Colestipol or colestyramine (to treat high cholesterol)
- Ergotamine and methysergide (to treat or prevent migraine)

If you have to take these other medicines/preparations as well as Tetracycline Tablets then try to take them as far apart as possible whilst continuing to follow the dosing instructions in the relevant Patient Information Leaflet.

Pregnancy and breast feeding:

If you are pregnant, planning to become pregnant or breast feeding ask your doctor or pharmacist for advice before taking any medicine. Tetracycline Tablets should not be taken during pregnancy or breastfeeding, as it could harm the baby.

Taking Tetracycline Tablets with food and drink:

You are advised not to take the tablets at the same time as milk, milk containing products, products derived from milk, or, food as this will reduce the effect of this medicine.

Important information about some of the ingredients of Tetracycline Tablets:

This medicine contains:

- Sunset yellow FCF (E110) which may cause allergic reactions.
- Lactose and sucrose. If you have previously been told by your doctor that you have an intolerance to some sugars, contact your doctor for advice before taking this medicinal product.
- Sodium – This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.



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3. How to take Tetracycline Tablets

Always take Tetracycline Tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Swallow the tablets one hour before or two hours after meals with a glass of water whilst sitting or standing. Do not take them immediately before going to bed.

The usual doses are for at least 10 days unless otherwise directed by your doctor:

- **Adults, Elderly and Children 12 years or over:**

General infections: The normal dose is 250 mg to 500 mg (1 to 2 tablets) every six hours (four times a day), depending on the severity of the condition. If you are elderly your doctor may prescribe you a lower dose (for example, if you suffer from a kidney problem) so that the level of tetracycline in your blood stream will be appropriate for the treatment of your complaint.

Specific infections:

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

Brucellosis: 2 tablets (500mg) four times a day with streptomycin.

Sexually transmitted diseases: 2 tablets (500mg) four times a day for between 7 and 30 days depending on your condition.

- **Children under 12 years old:**

Tetracycline Tablets are not recommended for use in children under 12 years of age as it can cause permanent discolouration of tooth enamel and affect bone development.

If you take more Tetracycline Tablets than you should:

If you take too much medicine or someone else has accidentally taken your medicine contact your doctor, pharmacist or local hospital straight away.

If you forget to take Tetracycline Tablets

Do not take a double dose to make up for one you have missed. Instead, you should continue with the following dose when it is due.

4. Possible side effects

Like all medicines Tetracycline Tablets can cause side effects although not everybody gets them. If, having taken these tablets, you experience any of the following then **STOP** taking these tablets **immediately** and then seek urgent medical advice:

- Allergic reactions. These include skin rashes – which may be itchy (see below for further information), swelling of the face, eye lids, lips and tongue, fever, sudden wheezing, chest pain or tightness (symptoms of inflammation of the membrane around the heart) or breathing difficulties and collapse (anaphylaxis).
- Symptoms of raised pressure in the skull: headaches, dizziness, 'ringing' in the ears and visual disturbances e.g. problems with seeing, blurred vision, "blind" spots, double vision. Permanent loss of vision has also been reported.
- Symptoms of a severe skin rash: this may include fever, blisters or ulcers, reddening, peeling or swelling of the skin.
- Severe or prolonged diarrhoea (which may be a sign of serious bowel inflammation).

Tell your doctor if you experience any of the following side effects:

Rare (affects fewer than 1 in 1,000 people)

- Liver failure, hepatitis (inflammation of the liver) and jaundice.
- Changes in the numbers and types of your blood cells. If you notice increased bruising, nosebleeds, sore throats, infections, 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.
- Ulceration/irritation/swelling of the oesophagus (gullet/throat) and dysphagia (difficulty in swallowing), usually when taken before bed or with inadequate fluid intake.
- Kidney failure, nephritis (may cause swollen ankles or high blood pressure).

Side effects with unknown frequency:

- Sensitivity to sunlight, which may result in skin discomfort or rashes which are red in colour. If affected avoid exposure to natural or artificial sunlight (such as a sun-bed). These rashes (which can have an itching/tingling/burning sensation) may be localised or more widely spread across the skin surface. Blisters, lesions or scaly skin may develop.
- An over-growth of resistant organisms which may cause infection/inflammation of the mouth, tongue, intestines and vagina.
- Stomach upsets such as nausea (feeling sick), vomiting (being sick) or diarrhoea.
- Loss of appetite.
- Oesophagitis and pancreatitis (inflammatory conditions affecting the oesophagus and pancreas - causing pain in the abdomen or back, feeling sick and fever).
- Pseudomembranous colitis (watery diarrhoea, fever and cramps).
- Skin rashes, which involve changes to the colour and texture of the skin.
- Discolouration of teeth (usually only noticeable after repeated doses).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing Tetracycline Tablets

- Store in a dry place below 25°C.
- Keep this medicine out of the sight and reach of children.
- Do not use after the expiry date shown on the package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Tetracycline Tablets contains:

- The active ingredient in this medicine is Tetracycline hydrochloride. Tetracycline 250mg Coated Tablets contains as its active ingredient: Tetracycline hydrochloride 270mg equivalent to 250mg of tetracycline.
- Other ingredients are lactose, pregelatinised starch, alginate acid, sodium starch glycolate, purified talc, sodium laurilsulfate, magnesium stearate, gelatin, sucrose syrup 70%, titanium dioxide (E171), sunset yellow FCF (E110), shellac, beeswax and carnauba wax.

What Tetracycline Tablets look like and contents of the pack:

- Tetracycline Tablets are orange, circular, sugar-coated tablets which come in one strength.
- Tetracycline Tablets are available in blister packs of 28 tablets and are only supplied to dispensing chemists, hospital pharmacies and other legally authorised users.

Marketing Authorisation Holder

Euro-Link Pharma Ltd., 110 Butterfield Innovation Centre and Business Base, Great Marlings, Luton LU2 8DL UK

Manufacturer

Surepharm Services Ltd, Bretby Business Park, Bretby, Burton-on-Trent, Derbyshire. DE15 0YZ

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