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Package leaflet: Information for the patient
Tetracycline 250 mg Tablets
 Tetracycline Hydrochloride

Read all of this leaflet carefully before you start taking 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. See section 4

What is in this leaflet

1. What Tetracycline Tablet is and what it is used for
2. What you need to know before you take Tetracycline Tablet
3. How to take Tetracycline Tablet
4. Possible side effects
5. How to store Tetracycline Tablet
6. Contents of the pack and other information

1. What Tetracycline Tablet is and what it is used for

These tablets contain the active ingredient, tetracycline hydrochloride. Tetracycline is a broad spectrum antibiotic which means it is effective against a variety of infections and organisms caused by bacteria. Tetracycline Tablets are used to treat a wide range of infections susceptible to tetracycline. These include chronic bronchitis; pneumonia or whooping cough, urinary tract infections (e.g. cystitis) and urethritis (inflammation of the tube which passes urine from the body) both which result in pain and difficulty urinating; severe acne; and venereal diseases such as syphilis, chlamydia and gonorrhoea; infections of the eye such as conjunctivitis; rickettsial infections such as Q fever or tick fever; other infections including brucellosis, psittacosis, plague, cholera; tetracycline may also be used to treat leptospirosis, gasgangrene and tetanus.

2. What you need to know before you take Tetracycline Tablet

Do not take Tetracycline Tablet:

- If you are allergic to Tetracycline Hydrochloride, other similar antibiotics (e.g. minocycline or doxycycline), or any of the other ingredients of this medicine (Listed in Section 6)
- If you have had liver or kidney problems for a long time or have severe kidney disease
- If you are pregnant or breastfeeding
- If you suffer from the condition systemic lupus erythematosus (SLE). This is an allergic condition which causes joint pain, rash (especially on the face), hair loss, malaise and fever.

Tetracycline should not be taken by children under the age of 12 years as it can cause permanent discolouration of growing teeth or poor growth of tooth enamel.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tetracycline Tablets.

- If you suffer from myasthenia gravis. This is a condition which causes muscle weakness, difficulty chewing and swallowing and slurred speech
- If you suffer from porphyria
- If you have kidney or liver disease
- If you are sensitive to sunlight

Other medicines and Tetracycline Tablet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Anti-coagulants to stop the blood clotting (e.g. warfarin or phenindione)
- The contraceptive pill. If you vomit or get diarrhoea, or if you lose blood when you are not expecting a period, your pill may not work properly and you will need to use other means of contraception e.g. a condom
- Ulcer healing drugs (e.g. sucralfate and tripotassium dicitratbismuthate)
- Ergotamine or methysergide (to treat or prevent migraine)
- Atovaquone (to treat pneumocystis pneumonia)
- Vitamin A
- Retinoids to treat acne and psoriasis (e.g. tretinoin, isotretinoin and acitretin)

- Antacids (indigestion remedies), any other medicines containing iron, calcium, bismuth, magnesium, aluminium or zinc salts (which may be included in vitamin and mineral supplements). Do not take at the same time as Tetracycline Tablet, as absorption of tetracycline may be reduced and tetracycline may reduce the absorption of zinc and oral iron

- Medicines to treat diabetes e.g. insulin, glibenclamide or gliclazide
- Diuretics (water tablets) e.g. furosemide
- Lithium to treat mental illness, bipolar disorder and depression
- Digoxin to treat heart problems, an uneven heartbeat (arrhythmia)
- Kaolin-pectin and bismuth subsalicylate (to treat diarrhoea)
- Strontium ranelate (to treat postmenopausal osteoporosis)
- Quinapril tablets which contain magnesium carbonate (to treat high blood pressure and congestive heart failure)
- Methotrexate (a cancer drug which can also be used to treat psoriasis and rheumatoid arthritis)
- Penicillin antibiotics e.g. amoxicillin, phenoxymethylpenicillin (to treat infections)
- Colestipol or colestyramine (taken to lower the amount of fats in your blood)
- Oral typhoid vaccine as the vaccine may be inactivated by tetracycline hydrochloride. The vaccine and Tetracycline Tablet should not be taken within 3 days of each other
- Methoxyflurane (an anaesthetic). If you need an operation tell your doctor or dentist you are taking Tetracycline Tablet
- You are taking drugs which you have been told can cause liver or kidney problems.

Other special warnings

Avoid exposure to strong sunlight or UV light (sunbeds), as you may experience photosensitivity reactions (e.g. skin rash, skin discomfort or easier burning). Consult your doctor if you notice any of these reactions.

If you are taking this medicine for a long time your doctor may want to carry out blood tests. This is quite usual and nothing to worry about.

Tetracycline Tablet with food and drink

Do not take the tablets at the same time as milk or food, as they can make the medicine less effective.

Pregnancy and breast feeding

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 taking this medicine as tetracycline hydrochloride could harm the baby

Driving and using machines

Tetracycline Tablets should not affect your ability to drive or operate machinery.

Tetracycline Tablet contains:

The tablet colouring contains Sunset Yellow (E110) which may cause allergic reactions.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking the tablets as they contain lactose and sucrose.

3. How to take Tetracycline Tablet

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

The tablets should be swallowed with a good drink of water. Some foods, milk and other dairy products can affect the absorption of this medicine. The tablets should be taken preferably 1 hour before or 2 hours after food. Swallow the tablets when standing or sitting down, do not take them immediately before going to bed.

The recommended dose is

For at least 10 days unless otherwise directed by your doctor:

Adults, Elderly and Children 12 years or over:
 General infections: 1 tablet (250mg) every 6 hours, you may be given 2 tablets (500mg) initially. For severe infections your doctor may increase your dosage to 500mg (2 tablets) every 6 hours.

Specific infections:

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

Continued, please turn over

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 Tablet than you should

You should contact your doctor or pharmacist straight away. Take your tablets or the pack with you so that the doctor knows what you have taken.

If you forget to take Tetracycline Tablet

If you have missed a dose you should take it within 2 hours of your usual time. If it is more than 2 hours since your dose was due, skip the missed dose and take your next one when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tetracycline Tablet

Do not stop treatment early as your infection may return if you do not finish the course of tablets. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Tetracycline Tablet and tell your doctor straightaway if you notice the following effects:

- Symptoms of an allergic reaction: skin rash which may be itchy, swelling of your face, eyelids, lips or tongue, sudden wheezing, chest pain or tightness, breathing difficulties, collapse.
- Chest pain, breathing difficulties, collapse or a dry cough since these may be symptoms of pericarditis (inflammation of the sac surrounding the heart)
- Symptoms of raised pressure in the skull: severe or persistent headaches, dizziness, ringing in the ears, visual problems including blind spots, double vision and blurred vision or in infants a bulging fontanelle (soft spot on the head), because these may indicate raised pressure inside the skull
- Worsening of the condition SLE (Systemic Lupus Erythematosus)
- A skin reaction like sunburn caused by photosensitivity (increased sensitivity to sunlight and UV light)
- Symptoms of a severe skin rash: this may include blisters or ulcers, swelling of skin, peeling, redness or discoloration, or Stevens-Johnson syndrome (symptoms are fever, blisters on the skin, eyes, mouth and genitals)
- Severe or prolonged diarrhoea which may have blood or mucus in it during or after treatment with Tetracycline Tablet, as this may be a sign of serious bowel inflammation
- A decrease in or loss of vision/eyesight.

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

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

- Inflammation of the liver (hepatitis) or liver failure or jaundice (symptoms may include yellowing of the skin or whites of the eyes, nausea, loss of appetite, stomach discomfort, confusion, reduced consciousness, pale stools or dark urine), transient increases in liver function test values (detected in blood tests)
- Swollen ankles or high blood pressure (caused by inflammation of the kidney (nephritis), sudden kidney failure (symptoms may include decrease or total loss in the amount of urine you produce)
- 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, 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
- Blood disorders including increased number of eosinophils (detected in blood tests), and severe reduction in the number of white or red blood cells which may cause fever or chills, severe fatigue, weakness, painful ulceration in the mouth, vagina or rectum, stomach ache, pale skin
- Swelling or ulceration of the oesophagus (gullet), particularly if the tablets are taken with insufficient water or at bedtime, difficulty swallowing
- Hearing disturbances.

Not Know (frequency cannot be estimated from the available data):

- Inflammation of the tongue or mouth, intestines or pancreas (causing discomfort or pain in the abdomen)
- Colitis (inflammation which causes abdominal pain, fever or diarrhoea)
- Kidney problems, or worsening of symptoms in patients who already have kidney problems (symptoms may be an increase or decrease in the amount of urine you produce or a change in frequency of passing urine, swelling in the legs or ankles), increased levels of urea in the blood
- Vaginal discharge, irritation or discomfort, thrush or irritation around your bottom and genital area
- Increased muscle weakness if you suffer from Myasthenia Gravis
- Feeling or being sick, diarrhoea, loss of appetite, stomach discomfort, discolouration of tooth enamel
- Headache, dizziness
- Fatty liver (causes tiredness, discomfort in your upper abdomen)
- Swollen tongue, sore or swollen mouth, sore throat
- Discoloured thyroid tissue (no changes in thyroid function are known to occur)
- If you suffer from SLE (Systemic lupus erythematosus) Tetracycline Tablets may make your symptoms worse
- Redness or colour change of the skin, raised, itchy, blistered or flaky skin, sensitivity to sunlight

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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. How to store Tetracycline Tablet

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package or container and keep tightly closed to protect the tablets from moisture.

Do not use this medicine after the expiry date which is stated on the carton or label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

If your doctor tells you to stop taking the tablets, please take any unused medicine back to your pharmacist to be destroyed.

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 Tablet contains:

Each coated tablet contains 250 mg of tetracycline hydrochloride as the active ingredient. The tablets also contain lactose, alginate, pregelatinised maize starch, sodium laurilsulfate, talc, magnesium stearate, sodium starch glycolate, sucrose, titanium dioxide (E171) and dispersed yellow Containing sunset yellow (E110).

What Tetracycline Tablet looks like and contents of the pack

The tablets are round and have an orange sugar coat. They are supplied to your pharmacist in packs containing 28, 100 or 1000 tablets. Not all pack sizes may be available.

Marketing Authorisation Holder

The product licence holder is RxPharma, Colonial Way, Watford, WD24 4YR.

Manufacturer: Surepharm Services Ltd.

Bretby, Burton upon Trent, Staffs, DE15 0YZ. UK.

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