What is in this leaflet

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4. Possible side effects
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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, these include:
- respiratory tract infections such as pneumonia, bronchitis 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 infections such as Q fever or tick fever
- other infections including brucellosis (headache, sickness, fever, swollen lymph nodes), cholera (severe sickness and diarrhoea), plague (painful swelling of the lymph nodes), psittacosis (headache, nose bleed, fever, rash, high fever), rickettsial infections such as Q fever or tick fever (severe headache, rash, high fever), other infections including brucellosis (headache, sickness, fever, swollen lymph nodes), psittacosis (headache, nose bleed, fever, rash, high fever), rickettsial infections such as Q fever or tick fever (severe headache, rash, high fever)
- tetanus (see page 2), a condition characterised by a rash (especially on the face), hair loss, weakness, difficulty chewing and swallowing and slurred speech
- tetralogy of Fallot, a condition characterised by a rash (especially on the face), hair loss, weakness, difficulty chewing and swallowing and slurred speech
- all allergic to tetracycline, other similar antibiotics (such as minocycline or doxycycline) or any other ingredients of this medicine (listed in section 6)
- have had kidney or liver problems for a long time or severe kidney disease
- have systemic lupus erythematosus (SLE), a condition characterised by a rash (especially on the face), hair loss, weakness, difficulty chewing and swallowing and slurred speech
- are giving it to a child under 12 years old.

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

Do not take Tetracycline tablets if you:
- are allergic to tetracycline, other similar antibiotics (such as minocycline or doxycycline) or any other ingredients of this medicine (listed in section 6)
- have had kidney or liver problems for a long time or severe kidney disease
- have systemic lupus erythematosus (SLE), a condition characterised by a rash (especially on the face), hair loss, weakness, difficulty chewing and swallowing and slurred speech
- are giving it to a child under 12 years old.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tetracycline tablets if you:
- suffer from myasthenia gravis, a condition characterised by muscle weakness, difficulty chewing and swallowing and slurred speech
- have kidney or liver disease
- are sensitive to sunlight

Children and adolescents

Tetracycline tablets should not be taken by children under 12 years of age as it can cause permanent discolouration of tooth enamel and affect bone development.

Other medicines and Tetracycline tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:
- penicillins 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 (to stop the blood clotting)
- diuretics (water tablets’ such as furosemide)
- kaolin-pectin and bismuth subsalicylate (to treat diarrhoea)
- medicines to treat diabetes such as insulin, glibenclamide or glipizide
- medicines which can damage your liver (check with your doctor or pharmacist to see if this applies to any medicines you are taking)
- methoxyflurane (an anaesthetic), if you need an operation, tell your doctor or dentist you are taking tetracycline
- atovaquone (to treat pneumonia)
- medicines such as antacids or other medicines containing aluminium, calcium, iron, magnesium, bismuth or zinc salts. Do not take at the same time as Tetracycline tablets, as absorption of tetracycline may be reduced
- 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 colestipolamine (to treat high cholesterol)
- ergotamine and methysgeride (to treat prevent migraine).

Tetracycline tablets with food and drink

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

Pregnancy, breastfeeding and fertility

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 could harm the baby.

Tetracycline tablets contain sunset yellow FCF (for osteoporosis)

Tetracycline tablets contain sunset yellow (E110) which may cause allergic reactions.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium-free.

**Tests**

During long-term treatment, blood, blood tests, and urine tests will be carried out.

**3 How to take Tetracycline tablets**

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

Swallow the tablets one hour before or two hours after meals, followed by a glass of water. Swallow the tablets when standing or sitting down, do not take them immediately before going to bed.

The recommended dose is:

- **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.
    - Bronchitis: 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.

**Use in children under 12 years old:**

Tetracycline tablets should not be used 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 (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

Symptoms of an overdose include feeling or being sick, crystals or blood in the urine, hypersensitivity reactions.

**If you forget to take Tetracycline tablets**

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

**If you stop taking Tetracycline tablets**

Do not stop treatment early as your infection may return if you do not finish the course of tablets.

**4 Possible side effects**

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

**Stop taking the tablets immediately** and seek urgent medical advice if the following occur:

- 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.
- Symptoms of raised pressure in the skull: headache, dizziness, 'ringing' in the ears, visual problems including blurred vision, "blind spots", double vision.
- Symptoms of a severe skin rash: this may include fever, blisters or ulcers, reddening, peeling or swelling of the skin.
- A decrease in or loss of vision/eyesight.
- Severe or prolonged diarrhoea which may have blood or mucus in it, during or after treatment with Tetracycline, as this may be a sign of serious bowel inflammation.
- Inflammation of the pancreas causing pain and tenderness in the abdomen and back (pancreatitis).

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

Rare (may affect up to 1 in 1,000 people)

- Inflammation of the liver (hepatitis), liver failure or jaundice (yellowing of the skin or whites of the eyes), 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, 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.
- Ulcers or swelling in the throat, difficulty swallowing.
- Kidney failure, nephritis (may cause swollen ankles or high blood pressure).

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

- Redness or colour change of the skin, raised, itchy, blistered or flaky skin, sensitivity to sunlight, thrush or irritation around your bottom and genital area.
- If you suffer from SLE (Systemic lupus erythematosus) tetracycline tablets may make your symptoms worse.
- If you suffer from myasthenia gravis tetracycline tablets may cause an increase in muscle weakness.
- Headache, feeling or being sick, diarrhoea, stomach upset, loss of appetite, discolouration of tooth enamel, inflammation of the tongue or mouth or intestines (causing discomfort or pain in the abdomen).
- Poor kidney function (changes in the need to or frequency to pass water, swelling in the legs or ankles).
- Fatty liver (causes tiredness, discomfort in your upper abdomen).
- Discoloured thyroid tissue (no changes in thyroid function are known to occur).
- Inflammation of the heart (pericarditis).

**Additional side effects in children:**

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

- Bulging fontanelles in infants (raised pressure in the skull)
- Thinning or low amount of tooth enamel.

**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 App Store.

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

**5 How to store Tetracycline tablets**

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

Do not store above 25°C and keep in the original package. If in a polypropylene container keep the container tightly closed.

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

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.

**Contents of the pack and other information**

**What Tetracycline tablets contain**

- The active substance is Tetracycline hydrochloride.
- Other ingredients in the tablet are sodium lauryl sulfate hydroxypropylcellulose (E463), colloidal silicon dioxide, croscarmellose sodium, magnesium stearate.
- The tablet coating contains methyldihydroxypropylcellulose (E464), propylene glycol, purified talc (E553), sunset yellow FCF aluminium lake (E110), titanium dioxide (E171), erythrosine (E127).

**What Tetracycline tablets look like and contents of the pack**

Tetracycline tablets are orange, circular, biconvex, film coated tablets which come in one strength. Each tablet contains 250mg of the active ingredient.

Pack size 28

Marketing Authorisation Holder and manufacturer

Accord, Barnstaple, EX32 9NS, UK

This leaflet was last revised in February 2020.

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**Tetracycline, Tablets, 250 mg, 28s - UK**

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**Non Printing Colours**

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| 3. |

**Pack size:** 28

**Pharmacode:** 8237

**Date Sent:** 13-12-19

**Technologist:** RH

**Technical Approval**

| Date sent | N/A |
| Date received | N/A |

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