PATIENT INFORMATION LEAFLET
OXYTETRACYCLINE 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 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 Oxytetracycline Tablets are and what they are used for

Oxytetracycline is a broad-spectrum tetracycline 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:
- lung 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 (severe headache, rash, high fever)
- other infections including 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 Oxytetracycline Tablets

Do not take Oxytetracycline Tablets if:
- You are sensitive to the tetracycline group of drugs or allergic to any of the other ingredients contained in these tablets. Allergy is more common in those people who are allergic to aspirin. An allergic reaction may be recognised as a rash, itching, swollen face or lips, or shortness of breath.
- You are suffering from a severe liver or kidney complaint or porphyria.
- You are pregnant or breast-feeding, unless instructed to do so by your doctor.
- 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).
- patients receiving vitamin A or retinoid therapy.

DO NOT GIVE TO CHILDREN UNDER 12 YEARS OLD.
Take special care with Oxytetracycline tablets and tell your doctor if:
- You suffer from myaestenia gravis, a condition characterised by muscle weakness, difficulty chewing and swallowing and slurred speech
- Have reduced kidney or liver function.

TELL YOUR DOCTOR OR PHARMACIST IF YOU ARE ALREADY TAKING OTHER MEDICINES.
See your doctor before you take Oxytetracycline Tablets if:
You are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Especially:
- penicillins such as amoxicillin (to treat infections)
- vitamin A
- retinoids such as acitretin, isotretinoin and tretinoin (to treat acne)
- drugs to thin the blood (anticoagulants)
- oral contraceptives (Oxytetracycline tablets may make the oral contraceptive pill less effective. You should use additional precautions whilst taking Oxytetracycline tablets and for 7 days after stopping.)
- diuretics ('water tablets' such as furosemide)
- kaolin-pectin and bismuth subsalicylate (to treat diarrhoea)
- medicines to treat diabetes such as insulin, glibenclamide or gliclazidemineral supplements or antacids.
- methoxyflurane (an anaesthetic), if you need an operation, tell your doctor or dentist you are taking Oxytetracycline
- medicines such as antacids or other medicines containing aluminium, calcium, iron, magnesium, bismuth or zinc salts, do not take at the same time as Oxytetracycline tablets, as absorption of Oxytetracycline may be reduced. Allow 2 to 3 hours between taking antacids and oxytetracycline.
- Lithium (to treat bipolar disorder, depression) since Oxytetracycline may cause an increase in serum lithium levels when taken at the same time as lithium containing medications

Taking with food or milk
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, planning to become pregnant or are breast feeding, ask your doctor or pharmacist for advice before taking any medicine as oxytetracycline should not be taken as it could harm the baby.

Tests
During long term treatment blood, kidney and liver tests will be carried out.

Driving and using machines
Oxytetracycline 250mg Coated Tablets will not affect your ability to drive or use machines.

Oxytetracycline 250mg Coated Tablets contains tartrazine, lactose and sucrose
- The tablet colouring includes tartrazine (E102), which can cause allergic-type reactions including asthma.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Oxytetracycline Tablets

- Your doctor has decided the dose that is best for you.
- Always follow your doctor's instructions exactly and those on the pharmacy label. If you do not understand anything ask your doctor or pharmacist.
- The tablets are for oral administration only and are to be swallowed with a glass of water either 1 hour before food or 2 hours after. Swallow the tablets when standing or sitting down. Do not take the tablets immediately before going to bed. Avoid exposure to natural or artificial sunlight as skin reactions may occur. Dairy products in particular will adversely affect the absorption of this medicine.
- They are suitable for adults, the elderly and children over 12 years old.

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: 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.
  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:**
  Oxytetracycline 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.

CONSULT YOUR DOCTOR IMMEDIATELY IF YOU HAVE TAKEN TOO MANY TABLETS.

If you have missed a dose, do not double-up on a dose to make up for the one you have missed.

4. Possible side effects

Like all medicines, oxytetracycline may cause side effects.

Stop taking the tablets **immediately** and seek urgent medical advice if the following occur:
- symptoms of an allergic reaction: skin rashes which may be itchy, swelling of the face and tongue. Fever and chest pain (symptoms of inflammation of the membrane around the heart) or breathing difficulties and collapse (anaphylaxis)
- symptoms of raised pressure in the skull: headache, visual problems including blurred vision, "blind" spots, double vision
- sensitivity to sunlight or artificial light such as sun-bed (symptoms such as tingling, burning or redness of the skin).

Tell your doctor if the following side effects occur:
- gastric upsets, such as feeling or being sick, diarrhoea and difficulty in swallowing and irritation of the oesophagus (gullet).
- pseudomembranous colitis (watery diarrhoea, fever and cramps).
- inflammation of the pancreas (pancreatitis, causing pain in the abdomen or back, feeling sick and fever)
- 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.
- Redness or colour change of the skin, flaky skin, thrush or irritation around your bottom and genital area. If you already suffer from SLE (systemic lupus erythematosus) Oxytetracycline tablets may make your condition worse
- Changes in liver or kidney function (tiredness, pain in the abdomen or back, difficulty passing urine) jaundice (yellow skin or eyes).
- an over growth of resistant organisms which may cause infection/inflammation of the mouth, tongue, intestines and vagina,
- skin rashes, which involve changes to the colour and texture of the skin,

If you notice these or indeed any unexpected reactions you should tell your doctor or pharmacist.

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 Oxytetracycline Tablets

- Store below 25ºC.
- Do not use after the expiry date shown on the package.
- Keep out of sight and reach of children

6. Contents of the pack and other information

What Oxytetracycline Tablets contain

The active substance is Oxytetracycline dihydrate 250 mg.

The other ingredients are lactose, pregelatinised starch, sodium lauryl sulphate, gelatin, magnesium stearate, talc, sucrose, titanium dioxide (E171), aluminium hydroxide and tartazine (E102), shellac, beeswax and carnauba wax.

What Oxytetracycline Tablets look like and contents of the pack
This product contains yellow, round, sugar-coated tablets. They are packed in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Esteve Pharmaceuticals Ltd, The Courtyard Barns, Choke Lane, Cookham Dean, Maidenhead, Berkshire SL6 6PT

Manufacturer: Surepharm Services Ltd, Bretby Business Park, Bretby, Burton upon Trent, DE15 0YZ.

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