actavis

Oxytetracycline tablets 250mg

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, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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What Oxytetracycline tablets are and what they are used for

Oxytetracycline belongs to a group of medicines called tetracycline antibiotics. It is also known as a broad-spectrum antibiotic and 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 diahorrea)
- leptospirosis (fever causing jaundice or meningitis), gas-gangrene and tetanus (lock jaw).

2 Before you take

Do not take Oxytetracycline tablets and **tell** your doctor if you:

 are allergic (hypersensitive) to oxytetracycline, other similar antibiotics (such as minocycline or doxycycline) or any other ingredient in the tablet (see section 6). The tablet contains sunset yellow (E110) which may cause allergic reactions

- have had **kidney** or **liver** problems for a long time
- have systemic lupus erythematosus (SLE), a condition characterised by a rash (especially on the face), hair loss, fever, malaise and joint pain

Do not give to a child under 12 years old.

Take special care with Oxytetracycline tablets and tell your doctor if you:

- suffer from myasthenia gravis, a condition characterised by muscle weakness, difficulty chewing and swallowing and slurred speech
- have reduced kidney or liver function.

Taking 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. Especially:

- penicillins such as amoxicillin (to treat infections)
- vitamin A
- retinoids such as acitretin, isotretinoin and tretinoin (to treat acne)
- oral contraceptives (the pill). Oxytetracycline tablets may make the oral contraceptive pill less effective. You should use additional contraceptive precautions whilst taking Oxytetracycline and for 7 days after stopping
- **anticoagulants** e.g. warfarin (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 gliclazide
- **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.

Pregnancy and breastfeeding

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.

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.

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3 How to take

Always take Oxytetracycline 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. Swallow the tablets when standing or sitting down and do not take them immediately before going to bed. Avoid exposure to natural or artificial sunlight as skin reactions may occur.

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.

If you take more 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.

If you forget to take the 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 the 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, Oxytetracycline tablets 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 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:

- Feeling or being sick, diarrhoea, stomach upsets, loss of appetite, discolouration of tooth enamel, difficulty swallowing, swelling or ulceration of the gullet.
 Pseudomembranous colitis (watery diarrhoea, fever and cramps)
- Inflammation of the pancreas (pancreatitis, causing pain in the abdomen or back, feeling sick and fever)

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- 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).

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight of children.

Store below 25°C in a dry place and in the original packaging. Do not use Oxytetracycline tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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

6 Further information

What Oxytetracycline tablets contain

- The active substance (the ingredient that makes the tablets work) is oxytetracycline dihydrate.
- The other ingredients in the tablet are magnesium stearate, maize starch, hydroxypropylcellulose (E463), colloidal silica, sodium lauryl sulphate.
- The tablet coating contains propylene glycol, sunset yellow (E110), quinoline yellow (E104), titanium dioxide (E171), methylhydroxypropylcellulose (E464), purified talc (E553).

What Oxytetracycline tablets look like and contents of the pack

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

Pack size is 28 tablets

Marketing Authorisation Holder and manufacturer

Actavis, Barnstaple, EX32 8NS, UK

This leaflet was last revised in February 2010.



