

Package Leaflet: Information for the user

OXYTETRACYCLINE TABLETS BP 250MG (Oxytetracycline dihydrate)

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

1. What this medicine is and what it is 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 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. What you need to know before you take this medicine

Do not take this medicine if:

- You are allergic to the tetracycline group of drugs or to any of the other ingredients of this medicine (listed in section 6). The tablet colouring includes tartrazine (E 102), which can cause allergic-type reactions including asthma. 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 problem 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).

- You are a patient receiving vitamin A or retinoid therapy.

Do not give to a child under 12 years old.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

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

Other medicines and Oxytetracycline

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

Oxytetracycline Tablets may interact with other medicines. You should tell your doctor if you are taking any of the following:-

- **penicillins** such as amoxicillin (to treat infections)
- **vitamin A**
- **retinoids** such as acitretin, isotretinoin and tretinoin (to treat acne)
- **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 mineral 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

Pregnancy, breast-feeding and fertility

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 and drink

- Do not take the tablets at the same time as milk or food, as they can make the medicine less effective.
- Tablets can be taken one hour before or two hours after meals

Important information about some of the ingredients of this medicine

- This medicine contains **SUCROSE** and **GLUCOSE**. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine
- This medicine contains **TARTRAZINE ALUMINUM LAKE (E102)** which may cause allergic reactions.

3. How to take this medicine

- Always take this medicine exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

SAME SIZE ARTWORK
120 x 260 mm

Front

- 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. Dairy products in particular will adversely affect the absorption of this medicine.
- 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 of this medicine 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 this medicine

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 this medicine

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 rashes and hives 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)
- loss of appetite
- 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 skin

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 Yellow Card Scheme Website: 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 this medicine

- Keep this medicine out of the sight and reach of children.
- Containers: Store in a cool dry place.
Blister packs: Store in a cool dry place. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. 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.

6. Contents of the pack and other information

What these tablets contain:

- Each tablet contains Oxytetracycline dihydrate equivalent to 250mg Oxytetracycline.
- The tablet core contains cellulose microcrystalline, alginate acid, povidone, magnesium stearate, stearic acid, maize starch.
The tablet coat contains sandarac, sucrose, glucose, purified talc, tartrazine aluminium lake (E102), titanium dioxide (E171), povidone, sodium benzoate and carnauba wax.

What these tablets look like and contents of the pack:

- The tablets are yellow coloured and sugar coated with a smooth polished surface.
- The tablets come in packs containing 10, 14, 28, 30, 56, 84, 100, 112 and 1000 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer

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