

OXYTETRACYCLINE 250 mg TABLETS

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 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, see section 4.

THIS LEAFLET CONTAINS

1. What Oxytetracycline is for
2. Before you take Oxytetracycline
3. How to take Oxytetracycline
4. Possible side effects
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6. Further information

1. WHAT OXYTETRACYCLINE IS FOR

Oxytetracycline belongs to a group of medicines called tetracycline antibiotics. It can be used to treat a wide range of bacterial infections, such as:

- infections of the lungs, including whooping cough, bronchitis and pneumonia
- urinary tract infections
- sexually transmitted diseases including chlamydia, gonorrhoea and syphilis
- skin infections including acne
- infections of the eye including conjunctivitis
- rickettsial infections (infections spread by lice, fleas and ticks) including Q fever and tick fevers
- other infections including brucellosis (an infection spread from infected animals through untreated milk or direct contact), psittacosis (an infection spread from birds), plague and cholera

If you are not sure why you have been prescribed these tablets then please ask your doctor.

2. BEFORE YOU TAKE OXYTETRACYCLINE

Do not take Oxytetracycline, and tell your doctor if you:

- are allergic to oxytetracycline, other tetracycline antibiotics, or any of the other ingredients in the tablets (listed in section 6 of this leaflet)
- have kidney problems
- are pregnant, planning a pregnancy or are breast-feeding
- are a child under 12 years of age
- are receiving treatment with vitamin A or retinoid medicines such as isotretinoin, tretinoin or acitretin
- have Systemic Lupus Erythematosus (SLE), an inflammatory disease which causes skin rashes, fever and joint pain

Warnings and precautions

Talk to your doctor before taking Oxytetracycline if you:

- have any problems with your liver
- have muscle weakness (myasthenia gravis)

Tests

If you are taking Oxytetracycline for a long time, your doctor may ask you to have some tests to check on your blood, kidneys and liver.

Taking Oxytetracycline can affect the results of some clinical tests. If you are going to have a test, it is important to tell your doctor or nurse that you are taking Oxytetracycline.

Other medicines and Oxytetracycline

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, even medicines bought without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they may affect how Oxytetracycline works:

- penicillin antibiotics to treat bacterial infections, such as amoxicillin, flucloxacillin or phenoxymethylpenicillin
- antacids to treat indigestion or heartburn, or over the counter medicines or supplements containing aluminium, calcium, iron, magnesium, bismuth or zinc. These medicines should not be taken at the same time as Oxytetracycline as they can affect the body's absorption of Oxytetracycline. You should allow 2-3 hours between doses of these medicines and Oxytetracycline.
- vitamin A
- retinoids to treat eczema, acne or other skin conditions, such as tretinoin or adapalene
- medicines to control diarrhoea, such as kaolin-pectin or bismuth subsalicylate
- medicines to treat diabetes, such as insulin gliclazide or tolbutamide
- medicines to increase urine production (diuretics), such as furosemide or spironolactone
- medicines to thin the blood and stop blood clots forming, such as warfarin or phenindione
- strontium ranelate to treat osteoporosis
- ergotamine to treat migraines

Oxytetracycline can make birth control pills less effective. You should use an additional form of contraception while you are taking Oxytetracycline and for 7 days after stopping.

If you go into hospital or have treatment for any other conditions, you must tell the doctor, dentist or nurse that you are taking Oxytetracycline.

Oxytetracycline with food and drink

Avoid taking this medicine at the same time as milk or food, in particular dairy products, as they can affect the body's absorption of Oxytetracycline.

Pregnancy and breast-feeding

Do not take Oxytetracycline if you are pregnant, planning a pregnancy or breast-feeding, unless your doctor has advised you to, as it may affect the development of your baby.

Ask your doctor for advice before taking any medicines.

Driving and using machines

Oxytetracycline is not known to affect the ability to drive or operate machinery.

Oxytetracycline contains sunset yellow (E110)

Oxytetracycline Tablets contain sunset yellow (E110) which may cause allergic reactions.

3. HOW TO TAKE OXYTETRACYCLINE

Always take Oxytetracycline exactly as your doctor has told you.

Swallow each tablet whole with a glass of water, ideally on an empty stomach, (either one hour before or two hours after a meal).

Do not take Oxytetracycline immediately before going to bed.

Dosage

Your doctor will decide your exact dose, as it depends on your condition.

Adults, elderly and children over 12 years: typical dose is 250 mg every six hours. If you have a severe infection, your doctor may increase your dose to 500 mg every six hours.

Children under 12 years: Oxytetracycline must not be used in children under 12 years old, as it can stain teeth and affect bone development.

If you take more Oxytetracycline than you should

Contact your doctor or go to the nearest hospital casualty department immediately. Take the package with you so the doctor knows what has been taken.

If you forget to take Oxytetracycline

Do not worry, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

If you stop taking Oxytetracycline

You should continue taking Oxytetracycline for as long as your doctor has told you to, even if you start to feel better. If you stop before finishing the prescribed course of treatment your infection may still be present or may reappear.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If you get any of the following serious side effects, STOP TAKING Oxytetracycline and contact your doctor or go to the nearest hospital casualty department immediately:

- allergic reactions, the symptoms of which may include itching, rash, swelling of the hands, feet, face, lips, tongue or throat, which can cause difficulty in swallowing or breathing
- increased pressure within the skull, which can cause severe headaches or problems with your vision
- swelling of the sac around the heart (pericarditis), the signs of which may include chest pain, difficulty breathing, fever and dry cough

If you get any of the following side effects, stop taking Oxytetracycline and tell your doctor as soon as possible:

- increased sensitivity to sunlight or artificial sunlight (sun-beds or sun-lamps) causing itching, stinging and burning of the skin.
You should limit your exposure to natural sunlight, and avoid exposure to artificial sunlight, where possible.
- changes to your blood, such as altered numbers of red blood cells, white blood cells, or blood platelets. This may cause symptoms including unexplained bleeding, bruising, increased risk of infections, sore throat, fever, weakness, breathlessness, pale skin and general illness. A blood test can be taken to check.

Tell your doctor if you get any of the following side effects:

- stomach upsets such as feeling sick (nausea), stomach ache, being sick (vomiting), diarrhoea. If you experience severe stomach upset you should take Oxytetracycline with food.
- loss of appetite, difficulty swallowing, inflammation of the digestive tract
- inflammation of the colon, which causes fever, severe diarrhoea and abdominal pain
- overgrowth of some resistant organisms causing infections, such as thrush, affecting the genitals or anus

- tooth discolouration. This is more common during long-term or repeated use of Oxytetracycline.
- inflammation or ulceration of the gullet, causing heartburn, sore throat, difficulty swallowing, nausea, vomiting or chest pain
- inflammation of the pancreas (pancreatitis), which can cause severe stomach pain that reached through to your back
- liver damage, inflammation of the liver (hepatitis), which causes yellowing of the skin and whites of the eyes (jaundice), liver failure, worsening of fat build-up within liver cells
- scaling and peeling of the skin
- problems with your kidneys, causing changes in your urine, tiredness, weakness, shortness of breath and swelling due to fluid retention
- worsening of the inflammatory disease Systemic Lupus Erythematosus (SLE), which causes skin rashes, fever and joint pain

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OXYTETRACYCLINE

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package or container and keep the container tightly closed.

Do not use these tablets after the expiry date, which is stated on the package or container. 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 contains

The active substance (the ingredient that makes the tablet work) in Oxytetracycline Tablets is oxytetracycline dihydrate. Each tablet contains 250 mg of oxytetracycline dihydrate.

The other ingredients are maize starch, pregelatinated maize starch, povidone, sodium starch glycolate, sodium lauryl sulphate, magnesium stearate, titanium dioxide (E171), quinoline yellow (E104), hydroxypropyl cellulose (E463), sunset yellow (E110), hypromellose, ethylcellulose and diethylphthalate.

What Oxytetracycline looks like and contents of the pack

Oxytetracycline 250 mg Tablets are pale yellow biconvex, film-coated tablets with the marking MP10 on one side.

The tablets come in blisters packs and containers of 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Genethics Europe Limited,
41 – 43 Klimentos, Klimentos Tower, Nicosia 1061, Cyprus

Manufacturer

DDSA Pharmaceuticals Limited
310 Old Brompton Road, London SW5 9JQ

For more information about this product, please contact the Marketing Authorisation Holder.

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