

Oxytetracycline Tablets BP 250 mg



PACKAGE LEAFLET: INFORMATION FOR THE USER

The name of this medicine is Oxytetracycline Tablets BP 250 mg which will be referred to as Oxytetracycline Tablets throughout this leaflet.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Oxytetracycline Tablets are and what they are used for
- What you need to know before you take Oxytetracycline Tablets
- How to take Oxytetracycline Tablets
- Possible side effects
- How to store Oxytetracycline Tablets
- Contents of the pack and other information

1. What Oxytetracycline Tablets are and what they are used for

These tablets contain the active ingredient, oxytetracycline dihydrate. Oxytetracycline belongs to a group of medicines called broad spectrum antibiotics. This means that it is active against a large number of bacteria which cause infections.

Oxytetracycline Tablets are used to treat a wide range of infections caused by bacteria. They are also used for preventing and treating chronic bronchitis, urinary tract (bladder and kidney) infections, pneumonia, brucellosis, pertussis and venereal diseases such as syphilis and gonorrhoea.

2. What you need to know before you take Oxytetracycline Tablets

- Do not take Oxytetracycline Tablets and tell your doctor if you:
- Are allergic to oxytetracycline (or any other medicine belonging to the tetracycline group of drugs) or you are allergic to any of the other ingredients of this medicine (listed in section 6)
 - Have long term kidney or liver problems
 - Suffer from (SLE) systemic lupus erythematosus (an allergic disease which affects the skin and internal organs -symptoms include red, scaly skin and swollen joints)
 - Are pregnant or breast-feeding (unless considered essential by your doctor) as oxytetracycline can affect the development of your baby
 - Are taking vitamin A or you are under retinoid therapy.

Oxytetracycline Tablets should not be taken by children under the age of 12 years.

You must be especially careful if:

- You have any liver problems or if you are taking any drugs which you have been told can cause liver problems
- You have the disease called myasthenia gravis (these tablets may increase muscle weakness).

If any of the conditions above apply to you, please discuss your treatment with your doctor before taking this medicine.

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before taking Oxytetracycline Tablets if you:
- Have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as it contains sucrose
 - Start to experience headaches or visual disturbances (which could be symptoms of benign intracranial hypertension).

- Take these tablets with another retinoid (a synthetic derivative of vitamin A) medicine, and you start to suffer from headache or eye problems, stop taking these tablets and consult your doctor
- Take special care if you are likely to be exposed to strong sunlight or UV light (sunbeds). You may experience photosensitivity reactions (e.g. skin rash or easier burning). If you do, stop taking the tablets straightaway
- Are taking this medicine for a long time your doctor may want to carry out blood tests. This is quite usual and nothing to worry about
- Gujsept sodium containing sodium methyl, sodium ethyl and sodium propyl hydroxybenzoate (E219, E215 and E217): may cause allergic reactions (possibly delayed)
- Sunset yellow FCF (E110): May cause allergic reactions
- Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Other medicines and Oxytetracycline Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Oxytetracycline Tablets can affect some other medicines you may be taking. Make sure your doctor knows if you are taking any of the following:

- Anticoagulants to prevent blood clotting (e.g. warfarin)
- 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
- Penicillin antibiotics such as amoxicillin, flucloxacillin
- Antacids (indigestion remedies) or preparations containing aluminium, calcium, magnesium, zinc or iron salts (which may be included in vitamin and mineral supplements). Do not take at the same time as Oxytetracycline Tablets, as absorption of Oxytetracycline may be reduced. Allow 2 to 3 hours between taking preparations containing these and Oxytetracycline
- Antidiarrhoeal medicines containing kaolin-pectin or bismuth subsalicylate
- Diuretics (to increase urine production) or any drug you have been told can cause kidney problems
- Medicines to treat diabetes such as insulin, glibenclamide or gliclazide
- Methoxyflurane (an anaesthetic). If you need an operation tell your doctor you are taking Oxytetracycline.
- Vitamin A
- Retinoids such as acitretin, isotretinoin and tretinoin (to treat acne).

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as those you have on prescription from your doctor.

Pregnancy and breast-feeding

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. Oxytetracycline Tablets may affect development of your baby.

Tests

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

Oxytetracycline Tablets 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.

Driving and using machines

Occasionally some people may find that their vision is temporarily affected. Do not drive or operate machinery if you have any problems with your eyesight.

Oxytetracycline Tablets contain Sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Oxytetracycline Tablets contain Sunset yellow FCF (E110), Sodium methyl, Sodium ethyl and Sodium propyl parahydroxybenzoate (E219, E215 and E217) May cause allergic reactions.

Oxytetracycline Tablets contain Sodium benzoate (E211) Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Oxytetracycline 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. The tablets should be swallowed with a full glass of water. Some foods, milk and other dairy products can affect the absorption of this medicine. The tablets should be taken preferably on an empty stomach (either 1 hour before food or 2 hours after) and do not take them immediately before going to bed. The doctor will decide what dose of tablets you need to take. The dose will be on the pharmacist's label. Carry on taking them for as long as you have been told unless you have any problems. In that case, check with your doctor.

The usual doses are as follows:

Adults, the elderly and children over 12 years

The usual dose is 1 or 2 tablets every six hours. Even if you feel better, continue taking the tablets for up to 3 days, as the infection may return.

Oxytetracycline Tablets should be used with caution in treatment of elderly patients.

Not to be given to children under 12 years old.

If you take more Oxytetracycline Tablets than you should You should contact your doctor or pharmacist straightaway. Take your tablets or the pack with you so that the doctor will know what you have taken.

If you forget to take a dose of Oxytetracycline Tablets

If it is more than 2 hours since your dose was due, skip the missed dose and take your next one when it is due. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Oxytetracycline Tablets

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

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

4. Possible side effects

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

Some side effects can be serious. Stop taking the tablets and tell your doctor immediately if you notice any of the following very rare symptoms:

- Wheezing or breathing difficulties which can lead to collapse, a rash, itching or hives on the skin, or sudden swelling of the face, throat, lips or genitals. These are signs of a severe allergic reaction
- Chest pain, breathing difficulties or a dry cough since these might be symptoms of pericarditis (swelling of the heart membrane)
- Headache and visual disturbances, or, in infants a bulging fontanelle (soft spot), because any of these may indicate raised pressure inside the skull
- A skin reaction like sunburn caused by photosensitivity (increased sensitivity to sunlight and UV light)
- Other serious skin reactions such as swelling or peeling, or Stevens-Johnson syndrome (symptoms are fever, blisters on the skin, eyes, mouth and genitals).

Tell your doctor, pharmacist or nurse if you suffer from any of the following effects:

Rare: may affect up to 1 in 1,000 people

- Swelling or ulceration of the oesophagus (gullet) (particularly if the tablets are taken with insufficient water at bedtime).

Not known: frequency cannot be estimated from the available data

- Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite
- Difficulty swallowing or swollen tongue
- Discolouration of tooth enamel
- Colitis (symptoms are colicky pain, diarrhoea or constipation)
- Kidney problems
- Harmful effects on the liver, including failure, hepatitis and jaundice (signs are yellow skin or eyes)
- Inflammation of the pancreas causing severe pain in the abdomen and back
- Severe reduction in the number of white or red blood cells and platelets which may cause fever or chills, severe fatigue, weakness, sore throat, pale skin, unusual bruising or bleeding, and make infections more likely
- Other allergic reactions such as skin rashes, itching and redness
- Worsening of the symptoms of SLE (systemic lupus erythematosus).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes 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. How to store Oxytetracycline Tablets

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

- Do not use this medicine after the expiry date which is stated on the carton or label. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original package or container and keep tightly closed to protect the tablets from light and moisture.

If your doctor tells you to stop taking the tablets, do not throw away any medicines via wastewater. 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 Oxytetracycline Tablets contain

The active substance in this medicine is oxytetracycline dihydrate. The other ingredients are Talc, Maize starch, Sodium lauryl sulphate, Magnesium stearate, Kaolin heavy, Shellac, Sucrose, Dextrin, Gelatin, Gujsept sodium containing sodium methyl, sodium ethyl and sodium propyl hydroxybenzoate (E219, E215 and E217), Titanium dioxide (E171), Instacoat colour containing sodium benzoate (E211), sunset yellow FCF (E110), quinoline yellow (E104) and indigo carmine (E132).

What Oxytetracycline Tablets look like and contents of the pack

The tablets are round, and have a yellow sugar coat. They are supplied to your pharmacist in blister packs sizes of 9, 10, 14, 15, 20, 21, 28, 30, 56 and 84 tablets or in opaque plastic containers pack sizes of 9, 10, 14, 15, 20, 21, 28, 30, 56, 84, 100, 250, 500 and 1000 tablets*.

*Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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