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| Title: | Oxytetracycline 250mg PIL | Colours (Printed) | Colours (Non printed) |
| Ref: | SURXP132KPB |  |  |
| Date: | 25/09/20 | | |
| Size (mm): | 297(H) x 148(W) | | |
| Modified: | 04/08/23 | | |

Main copy: Helvetica Neue Medium - 8pt

Section headings: Helvetica Neue Black - 9pt

Side 1

Side 2

Package leaflet: Information for the patient
Oxytetracycline Tablets BP 250 mg
This medicine will be called Oxytetracycline Tablets in 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, please 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Oxytetracycline Tablets are and what they are used for
2. What you need to know before you take Oxytetracycline Tablets
3. How to take Oxytetracycline Tablets
4. Possible side effects
5. How to store Oxytetracycline Tablets
6. 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. 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, severe acne, urinary tract (bladder and kidney) infections and venereal diseases such as syphilis and gonorrhoea.

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

Do not take Oxytetracycline Tablets if:

- You know 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 in this medicine (these are listed in section 6)
- You have long term kidney or liver dysfunction or porphyria
- You suffer from (SLE) 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 pregnant or breastfeeding (unless considered essential by your doctor) as oxytetracycline can affect the development of your baby
- You are taking Vitamin A or retinoid therapy.

Oxytetracycline Tablets should not be taken by children under the age of 12 years. It may cause permanent discolouration of tooth enamel and affect bone development.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Oxytetracycline Tablets if:

- You have any liver problems or if you are taking any drugs which you have been told can cause liver problems
- You have reduced kidney function

- You have the disease called myasthenia gravis (these tablets may increase muscle weakness, difficulty chewing and swallowing and slurred speech)
- If 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 (sun beds). You may experience photosensitivity reactions (e.g. skin rash or easier burning). If you do, stop taking the tablets straightaway
- If you 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.

Other medicines and Oxytetracycline Tablets

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

- Anticoagulants to prevent blood clotting (e.g. warfarin)
- The contraceptive pill, as your pill may not work properly and you may need to use a different method of birth control
- 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). Allow 2 to 3 hours between taking preparations containing these and oxytetracycline
- Anti-diarrhoeal 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.
- 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.

Oxytetracycline Tablets with food and milk

Do not take this medicine at the same time as having food, particularly dairy products including milk as they can reduce the absorption of this medicine.

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant, planning a pregnancy or you are breastfeeding, unless your doctor considers it essential as it may affect the development of your baby.

Driving and using machinery

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.

This medicine contains lactose, sucrose and tartrazine (E102):

- Tartrazine (E102) may cause allergic reactions.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium free.

3. How to take Oxytetracycline Tablets

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).

Always take this medicine exactly as described in this leaflet or as the doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Usual recommended dose:

Adults, the elderly and children over 12 years: The usual dose is 1 or 2 tablets every six hours. Do not stop taking the tablets until the course is finished, even if you feel better, as the infection may return.

For the treatment of acne, the usual dose is 1 tablet three times a day for four weeks, but longer courses may be given if considered necessary by your doctor.

Children

Not to be given to children under 12 years.

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.

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 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.

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
- Swelling/itching of the vulva and vagina, itching around the anus
- Discolouration of tooth enamel

- Colitis (symptoms are colicky pain, nausea, 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 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 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. How to store Oxytetracycline Tablets

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

Do not store above 25°C. Store in the original package or container and keep tightly closed to protect the tablets from moisture.

Do not use the tablets after the expiry date shown on the carton or label which is stated after EXP. The expiry date refers to the last day of that month.

If your doctor tells you to stop taking the tablets, take any left over back to your pharmacist to be destroyed. Do not throw away any medicines via waste water 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 Oxytetracycline Tablets contain

Each sugar coated tablet contains 250 mg of the active ingredient, oxytetracycline (as the dihydrate). Other ingredients are lactose, pregelatinised maize starch, sodium laurilsulfate, gelatin, talc, magnesium stearate, sucrose, titanium dioxide (E171), yellow colour containing tartrazine (E102) and dried aluminium hydroxide, and polish containing beeswax, carnauba wax and shellac.

What Oxytetracycline Tablets look like

The tablets are round, and have a yellow sugar coat. They are supplied to your pharmacist in packs of 28 tablets or in containers of 1000 tablets. Not all packs may be marketed.

Marketing Authorisation holder and manufacturer

The marketing authorisation holder is Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufactured by Surepharm Services Ltd., Bretby, Burton upon Trent, Staffs, DE15 0YZ, UK.

This leaflet was last revised in August 2023

If you would like the leaflet in a different format, please contact the marketing authorisation holder at the above address.

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