Cactavis

Doxycycline 50mg and 100mg capsules

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.

<u>In</u>dex

What Doxycycline capsules are and what they are used for

- 2 Before you take
- **3** How to take
- 4 Possible side effects
- 5 How to store
- 6 Further information

What Doxycycline capsules are and what they are used for

Doxycycline belongs to a group of medicines called tetracycline antibiotics. It is also known as a broadspectrum antibiotic and may be used **to treat** a wide range of infections caused by bacteria, these include:

- respiratory tract infections
- urinary tract infections
- sexually transmitted diseases
- skin infections such as acne
- infections of the eye
- · rickettsial infections such as Q fever or tick fever
- other infections such as malaria, cholera, brucellosis, leptospirosis, psittacosis and fevers caused by lice or ticks.

or prevent:

• travellers diarrhoea, scrub typhus and leptospirosis.

2 Before you take

Do not take Doxycycline capsules and **tell** your doctor if you:

- are allergic (hypersensitive) to doxycycline, other similar antibiotics (such as minocycline or tetracycline) or any of the other ingredients in the capsule (see section 6)
- are giving it to a child under 12 years old.

Take special care with Doxycycline capsules and **tell** your doctor if you:

- have liver disease or are taking medicines which affect your liver
- have porphyria (a genetic disorder of the blood)

- suffer from myasthenia gravis, a condition characterised by muscle weakness, difficulty chewing and swallowing and slurred speech
- are sensitive to sunlight
- have systemic lupus erythematosus (SLE) a condition characterised by a rash (especially on the face), hair loss, fever, malaise and joint pain.

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:

- warfarin or other anticoagulants (to stop the blood clotting)
- penicillin or rifampicin (to treat infections)
- medicines such as antacids containing aluminium, calcium or magnesium or other medicines containing iron, bismuth or zinc salts. Do not take at the same time as Doxycycline capsules, as absorption of doxycycline may be reduced.
- phenobarbital, carbamazepine, phenytoin or primidone (to treat epilepsy)
- oral contraceptives (the pill)
- methoxyflurane (an anaesthetic), if you need an operation, tell your doctor or dentist you are taking Doxycycline capsules
- ciclosporin (used following organ transplants).

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 doxycycline could harm the baby.

3 How to take

Always take Doxycycline capsules exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

You should **not drink alcohol** whilst taking Doxycycline capsules, speak to your doctor if you have any questions.

Swallow the capsules whole with a full glass of water, if the capsules irritate your stomach take them with food or milk. You should take the capsules either sitting down or standing up and well before you go to bed for the night to stop irritation and ulceration of your gullet. It is important not to lie down for at least thirty minutes after taking Doxycycline capsules.

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: 200mg on the first day as a single or two 100mg doses, followed by 100mg a day. For severe infections your doctor may increase the dose to 200mg a day.

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Specific infections:

- Acne vulgaris -50mg a day with food or fluid for 6-12 weeks.
- Sexually transmitted disease 100mg twice a day for 7-10 days
- Syphilis 300mg a day in divided doses for 10 days.
- Fevers caused by lice or ticks a single dose of 100-200mg depending upon severity of infection.
- Malaria 200mg a day for at least 7 days, should be given with other drugs such as quinine.
- Prevent infection with scrub typhus 200mg as a single dose.
- Prevent traveller's diarrhoea 200mg on the first day of travel followed by 100mg a day throughout the duration of the stay. Do not use for more than 3 weeks unless advised by your doctor.
- Prevent leptospirosis infections 200mg once a week throughout the stay in the infected area and 200mg at the end of the trip. Do not use for more than 3 weeks unless advised by your doctor.

Children under 12 years old:

Doxycycline capsules 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 capsules 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 capules

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 capsules

Do not stop taking the capsules because you feel better, it is very important to take all the capsules your doctor has prescribed for you, if you do not your condition may recur or get worse.

4 Possible side effects

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

Stop taking the capsules **immediately** and seek urgent medical advice if:

 you notice that your skin is very sensitive to light (you may get a skin rash, itching, redness or severe sunburn when out in sunlight or after using a sun bed).

Contact your doctor at once if the following reactions happen:

- wheeziness, difficulty in breathing, fever, sudden swellings of the face, lips, throat, tongue, hands or feet, fast heart rate, low blood pressure, rash or itching (especially affecting the whole body), pericarditis (inflammation of the membrane surrounding the heart)
- swollen tongue, watery diarrhoea, fever and cramps (pseudomembranous colitis), soreness and itching around the back passage and/or genital areas, inflammation around the vagina, or thrush of the vagina or mouth
- worsening of systemic lupus erythematosus (SLE).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Blood: altered numbers of certain types of blood cells, you
may notice that you bruise easily, have nose bleeds, or suffer
from infections and sore throats, porphyria (sensitivity of the
skin to sunlight, inflammation of nerves and stomach pains).

- **Glands and hormones**: discolouration of thyroid tissue (does not affect thyroid function).
- Central nervous system: headache, increased pressure in the skull (severe headaches, blurred and/or double vision, blind spots), permanent loss of vision, bulging fontanelles (soft spot on head) of infants.
- Ears: tinnitus (ringing or buzzing in the ears).
- Gastrointestinal tract: stomach pain, loss of appetite, feeling or being sick, heartburn, diarrhoea, difficulty swallowing, sore or painful tongue or mouth, inflammation and/or ulcers of the gullet, discolouration or underdevelopment of teeth.
- Liver: changes in liver function tests, inflammation of the liver (hepatitis), jaundice (yellowing of the skin or white of the eyes), liver failure and inflammation of the pancreas (pancreatitis)
- Skin: severe skin reactions such as erythema multiforme (circular, irregular red patches), Stevens-Johnson syndrome (rash with flushing, fever, blisters or ulcers), toxic epidermal necrolysis (reddening, peeling and swelling that resembles burns), detachment of the nail from the finger bed.
- Muscles and bones: muscle or joint pain.
- Kidneys: an increase in urea in the blood.

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: <u>www.mhra.gov.uk/yellowcard</u>

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store

Keep out of the sight and reach of children. Store below 25°C in a dry place.

Do not use Doxycycline capsules 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 Doxycycline capsules contain

- The active substance (the ingredient that makes the capsule work) is Doxycycline hyclate. Each capsules contains either 50mg or 100mg of Doxycycline base.
- The other ingredients are gelatin, magnesium stearate, shellac glaze, sodium lauryl sulfate, starch, E104, E127, E131, E171, E172 and propylene glycol.

What Doxycycline capsules look like and contents of the pack

Doxycycline 50mg are green and white hard gelatin capsules and Doxycycline 100mg are green hard gelatin capsules.

Doxycycline 50mg capsules are available in pack sizes of 28 capsules.

Doxycycline 100mg capsules are available in pack sizes of 8 & 50 capsules.

Marketing Authorisation Holder and Manufacturer

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