

PACKAGE LEAFLET: INFORMATION FOR THE USER

Doxycycline 50 mg Capsules Doxycycline 100 mg Capsules

Doxycycline

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 effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT DOXYCYCLINE IS AND WHAT IT IS USED FOR

Doxycycline capsules contain the active substance doxycycline as doxycycline hyclate. Doxycycline is an antibiotic belonging to a group of medicines called tetracycline. It is used to treat many different types of infections including

- Chest, lung or nasal infections e.g. bronchitis, pneumonia, sinusitis
- Urinary tract infections (the passage through which urine passes) e.g. cystitis, urethritis
- Acne (a skin condition)
- Sexually transmitted diseases e.g. gonorrhoea, syphilis, chlamydia
- Eye infections.
- Fevers associated with louse or tick bites
- Malaria, when chloroquine is not effective

Doxycycline capsules are also used to prevent certain infections developing, these are scrub typhus (a disease carried by small insects) Rocky Mountain spotted fever, travellers' diarrhoea, malaria and leptospirosis (a bacterial infection). Your doctor may want you to take Doxycycline capsules to treat another infection not listed above. You may also be prescribed an additional medicine to take with Doxycycline capsules to treat your infection. You must talk to your doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOXYCYCLINE

Do not take Doxycycline if you:

- Are **allergic** to doxycycline, other similar antibiotics (such as minocycline or tetracycline) or any of the other ingredients of this medicine (listed in section 6).
- are pregnant or trying to become pregnant
- are breast-feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Doxycycline if any of the following apply to you:

- you are likely to be exposed to strong sunlight or UV light (e.g. on a sun bed). You should avoid exposure to strong sunlight while taking this medicine as your skin may be more sensitive to sunburn than normal.
- you have kidney or liver problems.
- you have myasthenia gravis (a disease which causes unusual tiredness and weakness of certain muscles, particularly in the eyelid).
- you have porphyria (a rare disease of blood pigments)
- you have (or have ever had) systemic lupus erythematosus (an allergic condition that causes joint pain, skin rashes and fever). This condition may be worsened by taking Doxycycline capsules
- you are suspected of having syphilis. Your doctor will continue to monitor you after your treatment has stopped.
- you have diarrhoea or usually get diarrhoea when you take antibiotics or have suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using Doxycycline capsules tell your doctor immediately since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.
- you are taking oral retinoids as there is a higher risk of suffering from increased pressure in your skull (severe headache with change in vision) when taken with Doxycycline capsules.

When used for a long duration, Doxycycline capsules may cause infections that cannot be treated with this antibiotic. Your doctor can explain the signs and symptoms of such types of infection.

Children and adolescents

You should not use Doxycycline capsules during periods of tooth development (pregnancy, infancy or in children below 8 years old) as such use may lead to permanent discolouration (yellow-grey-brown). There may be circumstances (e.g. severe or life-threatening conditions), where your physician may decide that the benefits outweigh this risk in children below 8 years and Doxycycline capsules should be prescribed.

Other medicines and Doxycycline

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (including medicines you have obtained without a prescription).

If you are taking any of the medicines listed below tell your doctor before taking Doxycycline capsules.

Some medicines can reduce the effectiveness of Doxycycline capsules, these include:

- antacids (indigestion remedies), iron preparations, oral zinc or bismuth. These should not be taken at the same time of day as Doxycycline capsules.
- carbamazepine, phenytoin (medicines used to control epilepsy) and barbiturates (used to control epilepsy or as a sedative).

Doxycycline capsules can affect the action of some other medicines, these include:

- increased action of warfarin or coumarins (used to prevent blood clots)
- reduced effectiveness of oral contraceptives (birth control pills)
- reduced effectiveness of penicillin antibiotics (used to treat infections)
- increased blood levels of ciclosporin (a medicine used to affect the body's immune response)

If you are going to have a general anaesthetic for an operation or dental surgery you must tell your anaesthetist or dentist that you are taking doxycycline as you may have more side effects

Taking Doxycycline capsules with food, drink and alcohol

Please see section 3 How to take Doxycycline capsules. Alcohol may reduce the effect of Doxycycline capsules and should be avoided.

Pregnancy and breast-feeding

If you are pregnant, breast-feeding, think or may be pregnant or are planning to become pregnant ask your doctor or pharmacist for advice before taking any medicine as doxycycline could harm the baby.

Doxycycline Capsules must not be taken if you are pregnant or breast-feeding.

Driving and using machines

This medicine should not affect your ability to drive or use machines

Important information about some of the ingredients of Doxycycline

This medicine contains less than 1 mmol sodium (23 mg) per doxycycline 100 mg/ 50 mg capsule, that is to say essentially 'sodium-free'. Doxycycline 50 mg Capsules contain the colouring agent sunset yellow (E110) which may cause allergic reactions.

3. HOW TO TAKE DOXYCYCLINE

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

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 recommended doses are shown in the list below. These are the different doses that your doctor may prescribe depending on the infection being treated.

Usual Dose (Chest, lung or nasal, urinary tract, eye and other infections):

200 mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.

Children aged 8 years to less than 12 years:

Doxycycline for the treatment of acute infections in children aged 8 years to less than 12 years should be used in situations where other drugs are not available or are not likely to be effective. In such circumstances, the usual doses are:

For children 45 kg or less:

First day: 4.4 mg for each kg of bodyweight (in single or 2 divided doses) then 2.2 mg for each kg of bodyweight (in single or 2 divided doses) from the second day. The length of treatment is dependent on the infection being treated. In more severe infections, up to 4.4 mg for each kg of bodyweight should be given throughout treatment.

For children, over 45 kg:

Dose administered for adults should be used; 200 mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.

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Adults and Children aged 12 years to less than 18 years:

200 mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.

Acne: 50 mg daily with food or drink for 6-12 weeks.

Sexually transmitted disease: 100 mg twice a day for 7-10 days

Primary and Secondary Syphilis: 200 mg twice daily for 2 weeks. Your doctor will continue to monitor you after your treatment has stopped.

Fevers associated with louse or tick bites: single dose of 100-200 mg depending on severity.

Treatment of Malaria, when chloroquine is not effective: 200 mg a day for at least 7 days.

Prevention of malaria: 100 mg daily 1 – 2 days before traveling to a malarial area until 4 weeks after returning.

Prevention of scrub typhus: single dose of 200 mg.

Prevent traveller's diarrhoea: 100 mg twice daily on the first day of travel, followed by 100 mg daily throughout the stay in the area. If you are planning to take these capsules for more than 21 days, please consult your doctor.

Prevention of leptospirosis: 200 mg once each week during the stay in the area; 200 mg on completion of the trip. If you are planning to take these capsules for more than 21 days, please consult your doctor. You should start to feel better within a few days. If you have been given Doxycycline capsules for acne it may be a few weeks before you start to see an improvement. If your infection gets worse or you do not start to feel better within a few days (except for acne), or a new infection develops, go back and see your doctor.

Treatment of Rocky Mountain spotted fever:

Adults: 100 mg every 12 hours.

Children: weighing less than 45 kg: 2.2 mg/kg body weight given twice a day. Children weighing 45 kg or more should receive the adult dose. Patients should be treated for at least 3 days after the fever subsides and until there is evidence of clinical improvement. Minimum course of treatment is 5-7 days.

If you take more Doxycycline 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. Always take the labelled medicine package with you, whether there are any Doxycycline capsules left or not.

If you forget to take Doxycycline

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 Doxycycline

If you stop taking the capsules too soon, the infection may return. Take the capsules for the full time of treatment, even when you begin to feel better.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking this medicine and tell your doctor immediately if you experience any of the following serious side effects after taking this medicine. Although they are very rare, the symptoms can be severe.

- Sudden wheeziness, difficulty in breathing, chest pain, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- Upset stomach, loss of appetite, severe, persistent or bloody diarrhoea (this may occur up to two or three months after the last dose and may be associated with stomach pain or fever). This may occur after treatment with antibiotics and can be a sign of serious bowel inflammation.
- Fever, swollen lymph nodes or skin rash. These may be symptoms of a condition known as DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) and can be severe and life-threatening.
- Very severe headache which may be associated with visual disturbances such as blurred vision, double vision or loss of vision. Permanent visual loss has been reported.
- Serious illness with widespread severe blistering of the skin, mouth, eyes and genitals.

If any of the side effects listed below occur, contact your doctor as soon as possible

- The Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting doxycycline treatment for infections with spirochete such as Lyme disease.
- skin that is more sensitive to sunlight than normal (you may get a skin rash, itching, redness or severe sunburn when out in sunlight or after using a sun bed). If this happens stop taking the medicine and tell your doctor.
- Inflammation and/or ulcers of the gullet.
- Blood disorders. These are due to changes in numbers of different cell types in the blood. Symptoms may include tiredness, easy bruising or infections.
- Low blood pressure.
- Increased heart rate.
- Aches in the joints or muscles
- Stomach pain and diarrhoea.

The side effects listed below may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you:

Common: may affect up to 1 in 10 people

- feeling or being sick
- worsening of a disease called systemic lupus erythematosus (SLE). This is an allergic condition which causes joint pain, skin rash and fever headache
- pericarditis (inflammation affecting the heart)

Uncommon: may affect up to 1 in 100 people

- heartburn
- vaginal infection

Rare: may affect up to 1 in 1000 people

- anxiety
- difficulty in swallowing, sore or painful tongue or mouth
- skin reddening (flushing)
- a ringing or buzzing noise in the ear
- soreness and itching of the rectal and/or genital area
- inflammation of the bowel
- bulging fontanelles (soft spot on head) of infants
- increased pressure in the skull (severe headache with change in vision)
- inflammation and damage to the liver
- abnormal liver function tests
- discolouration of the thyroid tissue when given for long periods. The medicine does not impair thyroid function
- loosening of the nail from the nail bed after exposure to the sun
- increased levels of urea in the blood
- yellow skin and eyes (jaundice), inflammation of the pancreas
- upset stomach, loss of appetite, diarrhoea (this may occur up to two or three months after the last dose), stomach pain
- darker patches on your skin.

Not known: frequency cannot be estimated from the available data

- discolouration and/or lack of growth of teeth

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, 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 DOXYCYCLINE

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions. Do not use Doxycycline after the expiry date which is stated on the blister and carton. 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Doxycycline contains

- The active substance (the ingredient that makes the capsule work) is doxycycline hyclate.
- Each Doxycycline 50 mg Capsule contains 50 mg of the active substance doxycycline, the other ingredients are microcrystalline cellulose, talc, magnesium stearate, colloidal anhydrous silica and sodium lauryl sulphate. The capsule shell is made of gelatin. The colouring agents used in the capsule shell are titanium dioxide (E171), quinoline yellow (E104) and sunset yellow (E110).
- Each Doxycycline 100 mg Capsule contains 100 mg of the active substance doxycycline, the other ingredients are microcrystalline cellulose, talc, magnesium stearate, colloidal anhydrous silica and sodium lauryl sulphate. The capsule shell is made of gelatin. The colouring agents used in the capsule shell are titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132).

What Doxycycline looks like and the contents of the pack

Doxycycline 50 mg Capsules are white and yellow. They are available in the following pack sizes: 8, 16 and 28 capsules. Not all pack sizes may be marketed. Doxycycline 100 mg Capsules are white and blue. They are available in the following pack sizes: 8, 16, 28 and 50 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder and manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.

The distributor is Healthcare Pharma, 3, Young Place, Kelvin Industrial Estate, East Kilbride, Glasgow G75 0TD, United Kingdom.

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