



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 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 or pharmacist. 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 belongs to a group of medicines called tetracycline antibiotics. It is also known as a broad-spectrum 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 malaria, cholera, brucellosis, leptospirosis, psittacosis and fevers caused by lice or ticks.

or **prevent**:

- travellers diarrhoea, scrub typhus and leptospirosis.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOXYCYCLINE

### Do not take Doxycycline if you:

- are allergic to doxycycline, other similar antibiotic ( such as minocycline or tetracycline) or any of the other ingredients of this medicine (listed in section 6).
- are pregnant, breastfeeding, think or may be pregnant or planning to become pregnant, ask your doctor or pharmacist for advice before taking any medicine as doxycycline could harm the baby.

### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Doxycycline 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.

### Children and adolescents

Doxycycline capsules should not be use during periods of tooth development (pregnancy, infancy or in children below 8 years old) as it can cause permanent discolouration (yellow-grey-brown) or affect the proper growth of the teeth.

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 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.

- Warfarin or other anticoagulants (to stop blood clotting).
- Penicillin or rifampicin (to treat infections).
- medicines such as Antacids containing aluminium, calcium or magnesium, or other medicines containing iron, bismuth, zinc salts. Do not take at the same time as Doxycycline, as absorption of doxycycline may be reduced.
- Carbamazepine, phenytoin or primidone (to treat epilepsy)
- Methoxyflurane (an anaesthetic), if you need an operation, tell your doctor or dentist you are taking Doxycycline capsules
- Cyclosporin (used following organ transplants).

### Important information about some of the ingredients of Doxycycline

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.

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

### General infections:

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

## Adults, Elderly and Children aged 12 years to less than 18 years:

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.

The recommended dose is for at least 10 days unless otherwise directed by your doctor:

### 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.

### 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.

### 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

**Do not stop** taking Doxycycline 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.

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** 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 reaction happens:

- wheeziness, difficulty in breathing, fever, sudden swelling 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 of the rectal and/or genital area, inflammation around the vagina, or thrush of the vagina or mouth.
- worsening of systemic lupus erythematosus (SLE)
- 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)
- tinnitus (ringing or buzzing in the ears)
- inflammation of the liver (hepatitis), jaundice (yellowing of the skin or white of the eyes), liver failure and inflammation of the pancreas (pancreatitis)
- 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).
- 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.

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

- **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.
- **Gastrointestinal tract:** stomach pain, loss of appetite, feeling or being sick, heartburn, diarrhoea, difficulty in swallowing, sore or painful tongue or mouth, inflammation and/or ulcers of the gullet, discolouration and underdevelopment of teeth.
- **Liver:** changes in liver function tests
- **Skin:** detachment of the nail from the nail bed.
- **Muscles and bones:** muscle or joint pain.
- **Kidneys:** an increase in urea in the blood.
- **Psychiatric Disorders:** Anxiety

### 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](http://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).
- The active substance (the ingredient that makes the capsule work) is doxycycline hyclate. 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 Chanelle Medical U.K. Ltd.

**This leaflet was last revised in 09/2018**

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