



PATIENT INFORMATION LEAFLET

DOXYCYCLINE 100mg CAPSULES

Please read this leaflet carefully before you start to take this medicine.

- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Keep this leaflet; you may need to read it again.

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1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of your medicine is Doxycycline 100mg Capsules. It belongs to a group of medicines called tetracycline antibiotics. It may be used to treat a wide range of infections caused by bacteria, these include:

- Chest, lung or nasal infections e.g. bronchitis, pneumonia, sinusitis
- Infections of the kidneys and bladder e.g. cystitis, urethritis
- Infections of the skin such as acne
- Eye infections
- Sexually transmitted diseases e.g. gonorrhoea, syphilis, chlamydia
- Rickettsial infections such as Q fever or fevers associated with louse or tick bites
- Malaria, when chloroquine is not effective
- Other infections such as cholera, brucellosis, leptospirosis and psittacosis

Doxycycline capsules are also used to prevent certain infections developing such as scrub typhus, travellers' diarrhoea, malaria and leptospirosis (a bacterial infection caused by exposure to bacteria in fresh water contaminated by animal urine).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YOUR MEDICINE

Do not take your medicine and tell your doctor, if you:

- have taken Doxycycline or any other antibiotic before and suffered an allergic reaction (e.g. rash, itching, swelling of the face, fainting and breathing problems)
- are allergic to any of the other ingredients in Doxycycline Capsules (see section 6 Contents of the pack and other information)
- are pregnant or trying to become pregnant
- are breast-feeding

Warnings and Precautions

Talk to your doctor before taking Doxycycline if you:

- are likely to be exposed to strong sunlight or ultraviolet light (e.g. on a sunbed)
- have liver problems or are taking medicines which affect your liver
- have severe kidney problems
- have myasthenia gravis (a disease which causes unusual tiredness and weakness of certain muscles, particularly in the eyelid, difficulty chewing and swallowing and slurred speech)
- have porphyria (a rare genetic disease of blood pigments)
- have systemic lupus erythematosus (SLE) a condition characterised by a rash (especially on the face), hair loss, fever, malaise and joint pain. This condition may be worsened by taking Doxycycline.
- 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 **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 should not use Doxycycline 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) 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:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- Penicillin antibiotics (used to treat infections)
- Rifampicin (used to treat tuberculosis)

- Anticoagulants (used to thin the blood, e.g. warfarin)
- Quinapril (used to lower high blood pressure)
- Kaolin (used to treat diarrhoea)
- Sucralfate (used to treat and prevent stomach ulcers)
- Oral contraceptives ('The Pill'). This medicine may make the oral contraceptive pill less effective. You should use additional contraceptive precautions whilst taking this medicine and for 7 days after stopping.
- Barbiturates (strong sleeping tablets, e.g. phenobarbital)
- Ergotamine or methysergide (used to treat migraines or headaches)
- Typhoid vaccine (used to prevent typhoid fever if travelling to infected areas of the world)
- Carbamazepine, phenytoin, primidone or other drugs used to control epilepsy
- Ciclosporin (used to affect the body's immune response following organ transplants)
- Methoxyflurane (an anaesthetic). If you need an operation, tell your doctor or dentist that you are taking Doxycycline.
- Methotrexate (used to treat cancer, psoriasis or rheumatoid arthritis)
- Medicines such as antacids (indigestion tablets or liquids) containing aluminium, calcium, magnesium or other medicines containing iron, bismuth or zinc salts, should not be taken at the same time as your medicine, as absorption of your medicine may be reduced
- Retinoids (used to treat various skin conditions)

Doxycycline and Alcohol

Alcohol may reduce the effect of your medicine. It is therefore advisable to avoid drinking any alcohol.

Pregnancy and breast-feeding

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.

Driving and using machines

Do not drive or use machines if you suffer from visual disturbances such as blurring of vision while taking Doxycycline.

Important information about one of the ingredients in this medicine

Doxycycline 100mg Capsules 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.

3. HOW TO TAKE YOUR MEDICINE

Always take your medicine exactly as your doctor has instructed you. You should check with your doctor or pharmacist, if you are unsure.

Your medicine should be taken by mouth as follows:

- You must take your capsules as your doctor has told you to.
- It is important to swallow each doxycycline capsule whole with a glass of water.
- It is best to take your capsules at the same time(s) each day, when standing or while sitting.
- It is important not to lie down for at least thirty minutes after taking Doxycycline capsules, so that the capsule can move as swiftly as possible into the stomach and prevent irritation of the throat or oesophagus (canal taking food from the mouth to the stomach).
- If your stomach is upset, Doxycycline capsules can be taken with milk or a meal.

The recommended dose is:

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

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

Respiratory, urinary tract, ophthalmic and other infections

The usual dose is 200mg on the first day as a single dose or two 100mg doses, followed by 100mg daily. For severe infections your doctor may increase the dose to 200mg a day. The duration of treatment is dependent on the infection being treated.

Acne

50mg daily for 6-12 weeks, with food or fluid.

Sexually transmitted diseases

100mg twice daily for 7-10 days.

Primary and secondary syphilis

300mg daily in divided doses for at least 10 days.

Fevers associated with louse or tick bites

Single dose of 100mg or 200mg depending on severity.

Treatment of malaria, when chloroquine is not effective

200mg daily for at least 7 days.

Prevention of malaria

100mg daily for 1-2 days before travelling until 4 weeks after returning.

Prevention of scrub typhus

Single dose of 200mg.

Prevention of travellers' diarrhoea

100mg twice daily on the first day of travel, followed by 100mg 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

200mg once each week during the stay in the area; 200mg on completion of the trip. If you are planning to take these capsules for more than 21 days, please consult your doctor.

Doctors may prescribe different doses to these depending on the infection being treated. Check with your doctor if you are not sure why you have been prescribed the medicine.

The label on the pack will tell you what dose **YOU** should take, how often and for how long to take it. If you are still not sure, ask your doctor or pharmacist.

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 45kg or less:

First day: 4.4mg for each kg of bodyweight (in single or 2 divided doses) then 2.2mg 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 4.4mg for each kg of bodyweight should be given throughout treatment.

For children over 45kg:

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

Overdose: If you take more of your medicine 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 your medicine

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 your medicine

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

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking your medicine and tell your doctor immediately, or go to accident and emergency if you notice any of the following symptoms. Although the symptoms are very rare, they may be severe.

- A ringing or buzzing noise in the ear (tinnitus)
- 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)
- Symptoms of an allergic reaction - sudden wheeziness, difficulty in breathing, chest pain, fever, sudden swellings of the face, lips, tongue, throat, hands or feet, rash or itching (especially affecting the whole body), pericarditis (inflammation of the membrane surrounding the heart), worsening of systemic lupus erythematosus (autoimmune disease)
- 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.

If you experience any of the side effects listed below, tell your doctor as soon as possible:

- Sensitivity to sunlight - you may get a skin rash, itching, redness or severe sunburn when out in sunlight or after using a sun bed
- 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
- Swollen tongue, severe watery or bloody diarrhoea, fever and cramps (pseudomembranous colitis), stomach pains
- Low blood pressure
- Aches in the joints or muscles
- Unusual rapid heartbeats (palpitations), fainting
- Blood disorders (symptoms may include tiredness, weakness, easy bruising or susceptibility to infection)
- Porphyria (sensitivity of the skin to sunlight, inflammation of nerves and stomach pains)
- Discolouration of thyroid tissue (does not affect thyroid function)
- Changes in liver function tests

- Hepatitis (inflammation of the liver)
- Liver failure
- An increase in urea in the blood
- Jaundice (yellowing of the skin or white of the eyes) has rarely been reported
- Pancreatitis (manifested by severe upper abdominal pain) has rarely been reported
- Loosening of the nail from the nail bed after exposure to the sun
- 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.
- Black hairy tongue
- Heartburn
- Anxiety

Not known: frequency cannot be estimated from the available data

- Discolouration and/or lack of growth of teeth

Most of these side effects are infrequent but if they persist or are troublesome you should see your doctor.

- Inflammation and/or ulcers of the gastrointestinal tract (symptoms may include sore mouth, indigestion and difficulty swallowing)
- Feeling or being sick, diarrhoea
- Loss of appetite
- Soreness and itching of the rectal and/or genital area
- Yeast infection around the anus or genitals

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 YOUR MEDICINE

Do not use your medicine after the expiry date shown on the blister and carton. The expiry date refers to the last day of that month.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Store below 25°C. Store in the original package. 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 your medicine contains

The active substance (the ingredient that make the capsules work) is doxycycline hyclate. The other ingredients in the capsule are sucrose, maize starch, crospovidone, Basic Butylated Methacrylate Copolymer (Eudragit E100) and Purified Talc.

The capsule shell contains gelatin and the colourings E171, E132 and E172.

The white printing contains shellac, propylene glycol, ammonium hydroxide, potassium hydroxide and the colour E171.

What your medicine looks like

Doxycycline capsules are opaque green capsules with "100mg" printed in white ink.

The capsules are available in packs of 8, 10, 14 and 50 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Kent Pharmaceuticals Limited, The Bower, 4 Roundwood Avenue, Stockley Park, Heathrow, United Kingdom, UB11 1AF.

Company responsible for release of this medicine

Kent Pharmaceuticals Ltd, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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Customer: CH **Originated by:** DOB (AWG)

Product: Doxycycline 100mg Capsules

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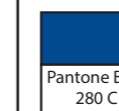
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Revision: Update to MAH address & Removal of Distributor address

ARTWORK FOR SUBMISSION
Supersedes: CP.DOX.100C.CH.V9P1

Colours



Pantone Blue
280 C