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 the elderly
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.
Fever 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 and 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 over 12 years of age
The recommended dosage schedule for children over 12 years of age, weighing 50 kg or less is 4 mg/kg of body weight on the first day of treatment (given as a single dose or divided into two equal doses with a 12 hour interval), followed by 2 mg/kg of body weight on subsequent days. For more severe infections up to 4 mg/kg of body weight may be used daily.

For children over 50 kg the usual adult dose should be used.

Children under 12 years of age
Doxycycline capsules are not recommended for use in children under 12 years of age as it can cause permanent discoloration of tooth enamel and affect bone development.

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:

- 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 heart), worsening of sytemic lupus erythematous (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:

- 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)
- 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 heart beats (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

Doxycycline (manifested by severe upper abdominal pain) has rarely been reported

- Discolouration or underdevelopment of teeth
- 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
- A ringing or buzzing noise in the ear

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 medicines 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 Purtified 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 Ltd, Repton Road, Measham, DE12 7DT, U.K.

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

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.

PL 08215/0009

This leaflet was last revised in September 2018.

CP.003.1606.DN V101