

Azithromycin 500mg Film-coated Tablets

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 side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Azithromycin is and what it is used for

Azithromycin belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to treat infections caused by micro-organisms like bacteria.

Azithromycin is used for the treatment of certain infections caused by bacteria that are sensitive to it, such as:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- ear infections
- skin and soft tissue infections, with exception of infected burn wounds e.g. - infection of the tube that carries urine from the bladder (urethra) or the neck of the womb (cervix) caused by *Chlamidia trachomatis* (bacteria).

2. What you need to know before you take Azithromycin

Do not take Azithromycin if:

- you are **allergic** to azithromycin dihydrate, erythromycin or any macrolide or ketolide antibiotic
- you are allergic to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Azithromycin if:

- you have severe liver or kidney problems
- you have severe heart problems or problems with your heart beat such as long QT syndrome (shown on an electro-cardiogram or ECG machine)
- your blood levels of potassium or magnesium are too low
- you develop signs of another infection
- you are taking any ergot derivatives such as ergotamine (to treat migraine) as these medicines should not be taken together with azithromycin (see section "Taking other medicines")
- you have a certain type of muscle weakness called myasthenia gravis
- you have nervous (neurological) or mental (psychiatric) problems.

Other medicines and Azithromycin

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- antacids - used for heartburn and indigestion. Azithromycin should be taken at least 1 hour before or 2 hours after the antacid
- ergotamine - (used for migraine) should not be taken at the same time as serious side effects may develop (with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain)
- cholesterol lowering medicines (statins)
- warfarin or similar medicines - used to thin the blood. Azithromycin can thin the blood even more
- cisapride - (used to treat stomach problems) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine)
- terfenadine - (used to treat hay fever) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine)
- zidovudine or nelfinavir - used to treat HIV infections. Taking nelfinavir with Azithromycin may mean that you get more of the side effects listed in this leaflet
- rifabutin - used to treat tuberculosis (TB)
- quinidine - used to treat heart rhythm problems
- cyclosporin - used to stop your body rejecting an organ transplant. Your doctor will regularly check your blood levels of cyclosporin and may change your dose.

Tell your doctor or pharmacist if you are taking any of the following medicines. Azithromycin can make the effects of these other medicines stronger. Your doctor may change your dose:

- alfentanil - a painkiller used e.g. during operations
- theophylline - used for breathing problems such as asthma and chronic obstructive pulmonary disease (COPD)
- digoxin - used to treat heart problems
- astemizol - used to treat hay fever
- pimozide - used to treat mental health problems.

Azithromycin with food and drink

This medicine can be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is insufficient information available about the use of azithromycin during pregnancy. Therefore you should not use Azithromycin during pregnancy, unless explicitly advised by your doctor.

Azithromycin is partially passed through the mother's milk. It is not known whether azithromycin may have adverse effects on the breast-fed infant. Breast-feeding should therefore be discontinued during treatment with Azithromycin. It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. Breast-feeding may be resumed thereafter.

Driving and using machines

There are no data available about the influence of azithromycin on the ability to drive or operate machines. However azithromycin tablets may cause dizziness and seizures so make sure you are not affected before driving or operating machinery.

Azithromycin contains lactose

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 Azithromycin

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

The recommended dose**For adults, children and adolescents with a body weight of 45kg or over**

500mg once daily for three days with a total dose of 1500mg. Alternatively, your doctor may decide to prescribe the total dose of 1500mg over a period of 5 days, with 500mg the first day and 250mg on days 2 to 5.

For infections of the neck of the womb and urethra caused by Chlamydia trachomatis

One dose of 1000mg, to be taken one time.

Children and adolescents under 45kg

The tablets are not recommended. Young people with a body weight of less than 45kg should use other forms of this medicine.

Patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

Dosage for elderly

For elderly the same dosage as for adults applies.

Method of administration:

The tablets can be taken with or without food. The tablets should be taken with ½ glass of water.

If you take more Azithromycin than you should

If you have taken too much Azithromycin, contact your doctor, pharmacist or go to your nearest hospital at once. Symptoms of overdose are loss of hearing, feeling sick or being sick and diarrhoea. In case of overdosage admission into hospital may be necessary.

If you forget to take Azithromycin

If you forget to take Azithromycin, take your dose as soon as possible. If it is almost time for the next dose, just skip that dose and take the next one when it is due. If in doubt, please contact your doctor or pharmacist. If you have to skip a dose, still take all of your tablets. This means that you will finish your course a day later.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Azithromycin

Never stop the treatment with Azithromycin on your own, but first discuss this with your doctor. If the prescribed treatment is not completely finished, the infection may come back again.

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.

If you have any of the below symptoms of a severe allergic reaction stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital.

Not known (frequency cannot be estimated from the available data)

- Sudden difficulty in breathing, speaking and swallowing
- Swelling of the lips, tongue, face and neck
- Extreme dizziness or collapse
- Severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs
- Skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) as they may be signs of a hypersensitivity reaction (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

If you experience any of the following side effects contact your doctor as soon as possible

- Rare (may affect up to 1 in 1,000 people)
- Increased or reduced urine output, or traces of blood in your urine
 - Skin eruption that is characterised by the rapid appearance of red skin studded with small pustules (small blisters filled with white/ yellow fluid).

- Not known (frequency cannot be estimated from the available data)
- Diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation. This is something that can occasionally happen after taking antibiotics
 - Yellowing of the skin or whites of the eyes caused by liver problems
 - Inflammation of the pancreas, which causes severe pain in the abdomen and back
 - Skin rash caused by sensitivity to sunlight
 - Unusual bruising or bleeding
 - Irregular heart beat.

These are all serious side effects. You may need urgent medical attention.
Other side effects include

- Very common (may affect more than 1 in 10 people)
- diarrhoea
 - abdominal pain
 - feeling sick (nausea)
 - loose wind (flatulence).

- Common (may affect up to 1 in 10 people)
- lack of appetite (anorexia)
 - feeling dizzy
 - headache
 - sensation of pins and needles or numbness (paraesthesia)
 - changes in your sense of taste
 - visual impairment
 - deafness
 - being sick (vomiting), stomach pain or cramps, loss of appetite, problems digesting your food
 - skin rashes and itching
 - joint pain (arthralgia)
 - fatigue
 - change in the quantity of the white blood cells and the concentration of bicarbonate in the blood.

- Uncommon (may affect up to 1 in 100 people)
- thrush (candidiasis) - a fungal infection
 - bacterial infection
 - inflammation of the throat (pharyngitis)
 - breathlessness, chest pain, wheeze and cough (respiratory disorder)
 - inflammation of the mucous membrane inside the nose (rhinitis)
 - stomach flu (gastroenteritis)
 - inflammation inside your vagina (vaginitis)
 - pneumonia
 - reduction in the number of white blood cells
 - angioedema
 - hypersensitivity
 - nervousness
 - reduced sense of touch (hypoesthesia)
 - feeling drowsy (somnolence)
 - having difficulty sleeping (insomnia)
 - ear disorder
 - spinning sensation (vertigo)
 - hearing loss or ringing in your ears
 - palpitations
 - hot flushes
 - shortness of breath
 - nosebleed
 - inflammation of the lining of the stomach (gastritis)
 - constipation
 - difficulty swallowing
 - swollen abdomen
 - dry mouth
 - belching
 - mouth ulcer
 - increased salivary flow
 - liver problems such as hepatitis
 - allergic skin reactions such as being sensitive to sunlight, red, flaking and swollen skin
 - severe form of skin flushing
 - inflammation of the skin (dermatitis)
 - dry skin
 - increased sweating
 - pain, swelling and reduced motion in your joints (osteoarthritis)
 - muscle pain
 - back pain
 - neck pain
 - increase in blood urea levels
 - painful or difficult urination
 - pain in the upper back (renal pain)
 - spotting
 - testicular disorder
 - urticaria
 - chest pain
 - face swelling
 - fever
 - pain, numbness, muscle weakness, burning or tingling sensation (peripheral pain)
 - swelling (oedema)
 - general feeling of being unwell (malaise)
 - weakness (asthenia)
 - change in liver enzyme levels and blood levels
 - post procedural complications.

- Rare (may affect up to 1 in 1,000 people)
- feeling agitated, feeling of unreality to the self and own feeling
 - abnormal hepatic function
 - allergic skin reactions
 - swelling of the hands, feet, lips, genitals or throat (angioneurotic oedema)
 - kidney problems.

- Not known (frequency cannot be estimated from the available data)
- gut (colon) infection (pseudomembranous colitis)
 - reduced number of red blood cells due to destruction (haemolytic anaemia); reduction in number of platelets (thrombocytopenia)
 - anaphylactic reaction
 - feeling angry, aggressive
 - anxiety
 - confusion
 - hallucination
 - fainting (syncope)

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- fits (convulsions)
- feeling hyperactive
- change in your sense of smell (anosmia, parosmia)
- change in your sense of taste (ageusia)
- exacerbation or aggravation of muscle weakness (myasthenia gravis)
- rapid (ventricular tachycardia) or irregular heart beat, sometimes being life-threatening, changes of the heart rhythm found by an electro-cardiogram (QT prolongation and torsade de pointes)
- low blood pressure
- inflammation of the pancreas (pancreatitis)
- your tongue and teeth changes colour
- liver failure
- allergic skin reactions.

The following side effects have been reported in prophylactic treatment against Mycobacterium Avium complex (MAC):

- Very common (may affect more than 1 in 10 people)
- diarrhoea
 - abdominal pain
 - feeling sick (nausea)
 - loose wind (flatulence)
 - abdominal discomfort
 - loose stools.

- Common (may affect up to 1 in 10 people)
- lack of appetite (anorexia)
 - feeling dizzy
 - headache
 - sensation of pins and needles or numbness (paraesthesia)
 - changes in your sense of taste
 - visual impairment
 - deafness
 - being sick (vomiting), stomach pain or cramps, loss of appetite, problems digesting your food
 - skin rashes and itching
 - joint pain (arthralgia)
 - fatigue.

- Uncommon (may affect up to 1 in 100 people)
- reduced sense of touch (hypoesthesia)
 - hearing loss or ringing in your ears
 - palpitations
 - liver problems such as hepatitis
 - severe form of skin flushing
 - allergic skin reactions such as being sensitive to sunlight, red, flaking and swollen skin
 - general feeling of being unwell (malaise)
 - weakness (asthenia).

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 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 Azithromycin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

PVC/Alu blister: Store below 25°C. Store in the original packaging to protect from moisture.
OPA-PVC-Alu/Alu blister: This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Azithromycin contains

- The active substance is: Azithromycin dihydrate.
- Azithromycin 500mg Film-coated Tablets contain 500mg azithromycin (as dihydrate).
- The other ingredients are: Core: croscarmellose sodium (E468), magnesium stearate (E572), microcrystalline cellulose (E460), silicium dioxide, (E551), poloxamer, povidone (E1201), talc, and waterfree lactose. Coating: hypromellose (E464), hydroxypropylcellulose, macrogol and titanium dioxide (E171).

What Azithromycin looks like and contents of the pack

Film-coated tablet.
Azithromycin 500mg Film-coated Tablets are white to off-white oval, 9.7 x 17.9 mm, biconvex film-coated tablets marked “500” on one side and plain on the other side.

500mg tablets are available in a PVC/Alu and OPA-PVC-Alu/Alu blister of 2 and 3 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

MA holder
Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer
Actavis ehf
Reykjavíkurvegur 78
IS-220 Hafnarfjörður
Iceland

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If you would like a leaflet with larger text, please contact 01271 385257.



Actavis, Barnstaple, EX32 8NS, UK



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.

IN THIS LEAFLET

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

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, traveller's 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
- are giving it to a child under 12 years of age

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.

Take special care with your medicine

You should let your doctor know and ask their advice, 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.

Taking other medication

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)

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.

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. Do not take more than your doctor has recommended.

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.

DOSAGE

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.

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.

CP.DOX.100C.CH.V5P1

Customer: CH

Originated by: AWG MAT

Product: Doxycycline 100mg Capsules

Dimensions: 297mm x 210mm

Item Code: CP.DOX.100C.CH.V5P1

Proof No and Date: 1 10/11/2017

Revision:

ARTWORK FOR SUBMISSION

Supersedes: CP.DOX.100C.CH.V4P1

Colours



Pantone Blue
280 C

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 discolouration of tooth enamel and affect bone development.

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.

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 membrane surrounding the heart), worsening of systemic lupus erythematosus (autoimmune disease)

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)
- 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
- Pancreatitis (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.

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
- A ringing or buzzing noise in the ear
- 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. 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 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.

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