

PACKAGE LEAFLET

Package leaflet: Information for the patient

Doxycycline 100 mg Capsules, Hard

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 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
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1. What Doxycycline is and what it is used for

Doxycycline belongs to the tetracycline group of antibiotics. Doxycycline can be used to treat a variety of infections, including bacterial infections that affect the eyes, nose, throat and respiratory system (chest infections), eye infections, sexually transmitted diseases and infections of the urinary tract; malaria, fevers associated with lice, fleas and tick bites or diseases spread by animals (e.g. leptospirosis); and in the prevention of traveller's diarrhoea, scrub typhus, leptospirosis and malaria.

Your doctor may want you to take Doxycycline to treat another infection not listed above. You may also be prescribed an additional medicine to take with Doxycycline 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, a similar medicine or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant, trying to become pregnant or breast-feeding
- if you are a child under 12 years old, as tetracyclines can affect growing bones and teeth and can also cause staining and a reduction in the amount of enamel in the teeth

Warnings and precautions

Talk to your doctor or pharmacist before taking Doxycycline

- if you have kidney or liver problems
- if you suffer from a rare disorder called porphyria
- if you suffer from myasthenia gravis (a disease causing muscle weakness)
- if you have SLE (systemic lupus erythematosus)

Avoid strong sunlight or ultra violet light as Doxycycline can make the skin more sensitive. If your skin becomes red and patchy, tell your doctor as he may need to stop treatment.

If you are having tests, such as liver function tests or a urine test, tell your doctor you are taking Doxycycline.

If you are suspected as having syphilis. Your doctor will continue to monitor you after your treatment has stopped.

If 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 **tell your doctor immediately** since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembraneous colitis) which can occur following treatment with antibiotics.

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

Other medicines and Doxycycline

Tell your doctor if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines or any of the following:

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

- antacids, used for indigestion containing aluminium, calcium, magnesium
- sucralfate used to treat stomach or gut ulcers
- zinc sulphate
- bismuth
- preparations containing iron
- barbiturates used to control epilepsy or as a sedative e.g. phenobarbital
- antiepileptics e.g. carbamazepine, phenytoin

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

- Increased action of anticoagulants to thin the blood e.g. warfarin
- Reduced effectiveness of penicillin antibiotic used to treat infections
- Increased blood levels of ciclosporin used to affect the body's immune response following organ transplants
- Reduced effectiveness of oral contraceptives (birth control pills)

If you are going to have an operation and need an anaesthetic, tell the anaesthetist or dentist you are taking Doxycycline as you may have more side effects.

Doxycycline with alcohol

Please see section 3 on how to take Doxycycline.

Do not drink alcohol during treatment.

Pregnancy and breast-feeding

Do not take Doxycycline if you are pregnant, think you may be pregnant, or plan to become pregnant, as it can affect the development of your unborn baby.

Do not breast-feed if you are taking Doxycycline as doxycycline can pass into breast milk.

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.

Driving and using machines

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

3. How to take Doxycycline

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

You must complete the course of treatment as directed by your doctor, even if you feel better.

- Swallow the capsules with plenty of fluid.
- Take the capsules with milk or food to reduce the likelihood of stomach upset.
- Take whilst sitting or standing upright: this medicine **should not** be taken immediately before bedtime or if lying down.

Patients being treated for certain diseases may need monthly blood tests to check the infection is clearing up.

Adults and older people

The recommended dose is two capsules (200 mg) on the first day (either as a single dose or one capsule followed by a further 100 mg capsule 12 hours later), followed by one 100 mg capsule daily thereafter. To treat more serious infections your doctor may prescribe two capsules (200 mg) to be taken daily.

The following doses may be given to treat specific infections:

Sexually transmitted diseases: the recommended dose is 100 mg twice daily. Depending on the type of infection being treated, your treatment may continue for between 7 to 10 days.

Primary and secondary syphilis: the recommended dose is 200 mg twice a day for 2 weeks.

Louse and tick-borne fevers: the recommended dose is a single dose of 100 mg or 200 mg.

To treat malaria: (when chloroquine is not effective): the recommended dose is 200 mg daily for at least 7 days. Your doctor will also prescribe another medicine as well, possibly quinine, to help treat the disease.

To prevent malaria: the recommended dose is 100 mg daily starting 1 or 2 days before travelling to the malarial area. Treatment should continue during your visit and for 4 weeks after leaving the area.

To prevent scrub typhus: the recommended dose is a single dose of 200 mg

To prevent traveller's diarrhoea: the recommended dose is 200 mg as a single dose on the day of travel (or 100 mg followed by a second dose of 100 mg 12 hours later), then 100 mg daily throughout the stay (up to 3 weeks).

To prevent leptospirosis: the recommended dose is 200 mg once a week throughout the stay in the area and 200 mg on completion of the trip.

Use in children

Doxycycline **must not** be given to children under 12 years of age.

If you take more Doxycycline than you should

If you take more Doxycycline than you should contact your doctor or hospital emergency department immediately.

If you forget to take Doxycycline

If you forget to take a dose of Doxycycline take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Doxycycline

Do not stop taking Doxycycline without talking to your doctor first. It is important to finish the course of antibiotic as instructed by your doctor.

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 any of the following happen, **stop taking Doxycycline immediately and go to your nearest hospital emergency department:**

- Sudden wheeziness, difficulty breathing, chest pain, fever, swelling of the eyelids, face or lips, rash or itching (especially affecting the whole body)
- Severe skin reactions such as erythema multiforme (circular, irregular red patches), Stevens-Johnson Syndrome (fever, hives, blisters or ulcers on your skin or inside your mouth, nose, eyes and around your genitals) or Toxic epidermal necrolysis (reddening, peeling and swelling that resembles burns), severe shedding of skin, rash or itching (especially affecting the whole body)
- 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 headaches with changes in eyesight and blurred or double vision, or loss of vision. Permanent loss of vision has been reported
- Inflammation of the bowel which causes upset stomach, loss of appetite, severe, persistent or bloody diarrhoea
- Pericarditis (inflammation of the membrane around the heart)

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

- Inflammation and/or ulcers of the gullet
- Blood disorders, these are due to changes in the numbers of different cell types in the blood. Symptoms may include tiredness, easy bruising or injections.
- Haemolytic anaemia (low number of red blood cells). Signs include tiredness, headaches, being short of breath when exercising, dizziness with yellowing of the skin and/or eyes
- Low blood pressure
- Increased heart rate
- Aches in the joints or muscles
- stomach pain and diarrhoea.

Stop taking Doxycycline and tell your doctor if your skin becomes sensitive to sunlight or UV light. You may get a skin rash, itching, redness or severe sunburn.

Other side effects include:

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

Uncommon (may affect up to 1 in 100 people):

- heartburn
- dyspepsia
- gastritis
- Vaginal infection

Rare (may affect up to 1 in 1,000 people):

- upset stomach, loss of appetite, diarrhoea (this, may occur up to two or three months after the last dose), stomach pain
- 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
- thrush or fungal infections
- bulging fontanelles (soft spot on head) of infants
- 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
- Inflammation and damage to the liver. Signs include nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine
- Inflammation of the pancreas which causes severe pain in the abdomen and back

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

- discolouration and / or lack of growth of teeth

Your blood tests may show:

- reduction in the number of white blood cells
- a rise in blood urea
- abnormal liver function

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 DOXYCYCLINE

Keep out of the sight and reach of children.

Do not take Doxycycline after the expiry date which is stated on the label or carton after “EXP”. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. Store below 25°C.

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 to protect the environment.

6. Contents of the pack and other information

What Doxycycline contains

- The active substance is doxycycline hyclate, equivalent to 100 mg of doxycycline.
- The other ingredients are magnesium stearate, talc, maize starch. The capsule shell is made of gelatin and contains the colourings patent blue (E131), titanium dioxide (E171) and iron oxides (E172). The printing ink contains shellac, titanium dioxide (E171), propylene glycol, and either ammonium hydroxide and simeticone, or sodium hydroxide and povidone.

What Doxycycline looks like and the contents of the pack.

Your medicine comes as green capsules, containing yellow powder marked with “DE 100” with “G”.

Doxycycline is available in glass or plastic bottles or blister packs of 5, 7, 8, 10, 14, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100 and 250 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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