Package leaflet: Information for the user

Doxycycline 50 mg Capsules
Doxycycline 100 mg Capsules

(doxycycline hyclate**)**

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
6. Contents of the pack and other information

1. What Doxycycline is and what it is used for

The name of your medicine is Doxycycline 50 mg and 100 mg Capsules (referred to as Doxycycline in this leaflet). Doxycycline contains the active substance Doxycycline. Doxycycline is an antibiotic belonging to a group of medicines called tetracyclines. Doxycycline is used to treat many different types of infections including:

- Chest, lung or nasal infections e.g. acute worsening of chronic bronchitis, pneumonia, sinusitis
- Urinary tract infections (the passage through which urine passes) e.g. cystitis, urethritis
- Soft tissue and skin infection (including acne)
- Eye infections
- Sexually transmitted diseases e.g. gonorrhoea, syphilis, chlamydia
- Fevers associated with louse or tick-borne infections
- Malaria, when chloroquine is not effective
- Gangrene, tetanus, bacterial infections caught from contaminated water or certain animals (e.g. cattle, poultry and rodents).

Doxycycline capsules are also used to prevent certain infections developing, these are scrub typhus (a disease carried by small insects), travellers' diarrhoea, malaria and leptospirosis (a bacterial infection).

- Your doctor may want you to take Doxycycline capsules to treat another infection not listed above. You may also be prescribed an additional medicine to take with Doxycycline capsules 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 capsules:

- if you are allergic to doxycycline, any other tetracycline antibiotic or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or trying to become pregnant

- if you are breast-feeding

You should not use Doxycycline capsules 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 capsules should be prescribed.

Warnings and precautions
Talk to your doctor or pharmacist before taking Doxycycline if any of the following apply to you:
- you are likely to be exposed to strong sunlight or uv light (e.g. on a sun bed). You should avoid exposure to strong sunlight while taking this medicine as your skin may be more sensitive to sunburn than normal.
- you have kidney or liver problems.
- you have myasthenia gravis (a disease which causes unusual tiredness and weakness of certain muscles, particularly in the eyelid).
- you have porphyria (a rare disease of blood pigments).
- you have (or have ever had) systemic lupus erythematosus (an allergic condition that causes joint pain, skin rashes and fever). This condition may be worsened by taking Doxycycline capsules.
- you are suspected as having syphilis. Your doctor will continue to monitor you after your treatment has stopped.
- 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 capsules, **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 are taking oral retinoids as there is a higher risk of suffering from increased pressure in your skull (severe headache with change in vision) when taken with Doxycycline capsules.
- you have oesophagitis (inflammation of the oesophagus or gullet).

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

If you need to have tests on your urine be sure to let the doctor know you are taking Doxycycline capsules, as this medicine may affect the results of these tests.

Other medicines and Doxycycline
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines you have obtained without a prescription.
If you are taking any of the medicines listed below tell your doctor before taking Doxycycline capsules.

Do not take Doxycycline capsules:
- if you are taking penicillin for infection
- if you have the anaesthetic methoxyflurane.

Some medicines can reduce the effectiveness of Doxycycline capsules, these include:
- Antacids (indigestion remedies), iron preparations, oral zinc or bismuth. These should not be taken at the same time of day as Doxycycline capsules.
- Carbamazepine, phenytoin (medicines used to control epilepsy) and barbiturates (used to control epilepsy or as a sedative).

Doxycycline capsules can affect the action of some other medicines, these include:
- any drugs which prevent blood clotting (e.g. warfarin)

- reduced effectiveness of oral contraceptives (birth control pills), any antacids (indigestion remedies) containing calcium, aluminium or magnesium, or any iron preparations
- preparations containing zinc
- bismuth salts (used in the treatment of stomach ulcers and piles)
- carbamazepine or phenytoin (treatments for epilepsy), or any barbiturates (sedatives)
- ciclosporin, a drug used to suppress the body's natural defences against infection
- Tell your doctor or dentist you are taking Doxycycline if you are due to have surgery (including dental procedures) requiring anaesthetic, as the dose of Doxycycline may need to be reduced or stopped before have an anaesthetic.

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Taking Doxycycline with food, drink and alcohol
Please see section 3 How to take Doxycycline.
Alcohol may reduce the effect of Doxycycline capsules and should be avoided.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, as this medicine can cause problems with the colour and development of teeth and the bone development of the unborn child or young infant.

Ask your doctor or pharmacist for advice before taking this medicine.

Doxycycline capsules must not be taken if you are pregnant or breast-feeding.

Driving and using machines
This medicine should not affect your ability to drive or use machines.

3. How to take Doxycycline

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 capsules should be swallowed with plenty of water.
- It is best to take your capsules at the same time(s) each day, when sitting or while standing.
- 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).
- For the treatment of infections, Doxycycline capsules can be taken with or without food.
- For the treatment of acne, it is recommended to take Doxycycline capsules with food or a drink.
- If Doxycycline capsules upset your stomach, then taking it with food or milk is recommended.

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.

- **Usual Dose (Chest, lung or nasal, urinary tract, eye and other infections)**
  200 mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.
- **Acne**
  50 mg daily for 6-12 weeks, with food and a drink.
- **Sexually Transmitted Diseases**
  100 mg twice daily for 7 - 10 days.
- **Primary and Secondary Syphilis**
  200 mg twice daily for 2 weeks. Your doctor will continue to monitor you after your treatment has stopped.
- **Fevers associated with louse or tick bites**

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

- **Treatment of malaria, when chloroquine is not effective**
  200 mg daily for at least 7 days. You will also be given another medicine as well as Doxycycline capsules for this infection.
- **Prevention of malaria**
  100 mg daily from 1-2 days before travelling to a malarial area until 4 weeks after returning.
- **Prevention of scrub typhus**
  Single dose of 200 mg.
- **Prevention of travellers' diarrhoea**
  100 mg twice daily on the first day of travel, followed by 100 mg 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**
  200 mg once each week during the stay in the area; 200 mg on completion of the trip. If you are planning to take these capsules for more than 21 days, please consult your doctor.

- Rocky Mountain spotted fever
Adults: 100 mg every 12 hours.
Children: weighing less than 45 kg: 2.2 mg/kg body weight given twice a day. Children weighing 45 kg or more should receive the adult dose. Patients should be treated for at least 3 days after the fever subsides and until there is evidence of clinical improvement.
Minimum course of treatment is 5-7 days.

You should start to feel better within a few days. If you have been given Doxycycline capsules for acne it may be a few weeks before you start to see an improvement. If your infection gets worse or you do not start to feel better within a few days (except for acne), or a new infection develops, go back and see your doctor.

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

Adults and children aged 12 years to less than 18 years:
200 mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.

If you take more Doxycycline than you should
If you (or someone else) swallow a lot of the capsules all together, or if you think a child has swallowed any of the capsules,, contact your doctor or nearest hospital immediately. Please take this leaflet and the labelled medicine package with you, whether there are any Doxycycline capsules left or not.

If you forget to take Doxycycline
If you forget to take a capsule, take it as soon as you can. Take your next capsule at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Doxycycline
You should continue to take these capsules for as long as your doctor tells you to. Take the full course. Even if you start to feel better the original infection may still be present and may recur if treatment is stopped.

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.

Serious side effects
Stop taking Doxycycline and see a doctor or go to a hospital straight away if you notice the following side effects after taking this medicine. Although they are very rare, the symptoms can be severe.
- Sudden wheeziness, difficulty in breathing, chest pain, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- Upset stomach, loss of appetite, severe, persistent or bloody diarrhoea (this may occur up to two or three months after the last dose and may be associated with stomach pain or fever). This may occur after treatment with antibiotics and can be a sign of serious bowel inflammation.
- Very severe headache which may be associated with visual disturbances such as blurred vision, double vision or loss of vision. Permanent visual loss has been reported.
- Serious illness with widespread severe blistering of the skin, mouth, eyes and genitals. This may be due to Stevens-Johnson Syndrome, drug reaction with eosinophilia and systemic symptoms (DRESS) such as 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 or toxic epidermal necrolysis, which are serious illnesses. Also, the separation of the distal nail from the nail bed.
- worsening of the symptoms of systemic lupus erythematosus (SLE) an autoimmune condition which causes joint pain, skin rash and fever.
- Increased pressure in the brain.

If any of the side effects listed below occur, contact your doctor as soon as possible.
- 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.
- Skin that is more sensitive to sunlight than normal. You may get a skin rash, itching, redness or severe sunburn. If this happens stop taking the medicine and tell your doctor.
- Inflammation and/or ulcers of the gullet.
- Blood disorders. These are due to changes in numbers of different cell types in the blood. Symptoms may include tiredness, easy bruising or infections.
- Low blood pressure.
- Increased heart rate.
- Aches in the joints or muscles.
- Stomach pain and diarrhoea.

Other side effects
The side effects listed below may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you:

Common (may affect up to 1 in 10 people)
- feeling or being sick
- worsening of a disease called systemic lupus erythematous (SLE). This is an allergic condition which causes joint pain, skin rash, fever and headache
- pericarditis (inflammation affecting the heart)

Uncommon (may affect up to 1 in 100 people)
- heartburn
- vaginal infection

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

- anxiety
- 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
- bulging fontanelles (soft spot on head) of infants
- increased pressure in the skull (severe headache with change in vision)
- inflammation and damage to the liver
- abnormal liver function tests
- discolouration of the thyroid tissue when given for long periods. The medicine does not impair thyroid function
- round or oval patches of redness and swelling of the skin which reappear at the same site each time the medicine is taken (fixed eruption)
- loosening of the nail from the nail bed after exposure to the sun
- increased levels of urea in the blood
- yellow skin and eyes (jaundice), inflammation of the pancreas
- upset stomach, loss of appetite, diarrhoea (this may occur up to two or three months after the last dose), stomach pain
- darker patches on your skin

Not known: frequency cannot be estimated from the available data
- discolouration and/or lack of growth of teeth

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 Doxycycline

Keep all medicines out of the sight and reach of children

Do not store above 25ºC. Keep in the original package and store in a dry place.

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

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.

If your capsules become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Doxycycline contains

The active ingredient is Doxycycline Hyclate.
Each Doxycycline 50 mg capsule contains 50 mg of doxycycline equivalent to approximately 57.71 mg of doxycycline hyclate.

Each Doxycycline 100 mg capsule contains 100 mg of doxycycline equivalent to approximately 115.41 mg of doxycycline hyclate.

The other ingredients are: Hypromellose, Sodium lauryl sulphate, Microcrystalline cellulose, Magnesium stearate. The capsule shell contains: gelatin and titanium dioxide (E171).

Doxycycline 100 mg capsules also contain Brilliant Blue (E133) and Iron Oxide Yellow (E172).

What Doxycycline looks like and contents of the pack
Doxycycline 50 mg capsules are unmarked, hard, white coloured capsules.
Doxycycline 100 mg capsules are unmarked, hard, green coloured capsules.

Doxycycline 50 mg capsules are available in blister packs of 14 and 28 capsules.
Doxycycline 100 mg capsules are available in blister packs of 8, 14 and 50 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom

Manufacturer
Waymade PLC, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom

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