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PACKAGE LEAFLET: INFORMATION FOR THE USER

Doxycycline 100mg 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

- What Doxycycline 100mg Tablets are and what they are used for
- What you need to know before you take Doxycycline 100mg Tablets
- How to take Doxycycline 100mg Tablets
- Possible side effects
- How to store Doxycycline 100mg Tablets
- Contents of the pack and other information

1. WHAT DOXYCYCLINE 100MG TABLETS ARE AND WHAT THEY ARE USED FOR

Doxycycline 100mg Tablets contain the active substance doxycycline. It belongs to a group of medicines called tetracycline antibiotics. It is used to treat a wide variety of bacterial infections.

Doxycycline 100mg Tablets are useful for the treatment of infections including:

- Chest, lung or nasal infections e.g. bronchitis, pneumonia, sinusitis
- Urinary tract infections (the passage through which urine passes) e.g. cystitis, urethritis
- Skin infections such as acne
- Infections of the eye
- Soft tissue infections
- Infections of the digestive tract
- Other infections including psittacosis (parrot fever)
- Sexually transmitted infections e.g. gonorrhoea, syphilis, chlamydia
- Rickettsial infections - fevers associated with louse or tick bites such as Q fever or tick fever.
- Malaria, when chloroquine is not effective.

These tablets can also be used to prevent certain infections developing, these are scrub typhus (a disease carried by small insects) Rocky Mountain spotted fever, travellers' diarrhoea, malaria and leptospirosis (a bacterial infection).

Your doctor may want you to take Doxycycline 100mg Tablets to treat another infection not listed above. You may also be prescribed an additional medicine to take with Doxycycline 100mg Tablets 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 100MG TABLETS

Do not take Doxycycline 100mg Tablets:

- If you are allergic to doxycycline or 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 100mg Tablets 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 doctor may decide that the benefits outweigh this risk in children below 8 years and Doxycycline 100mg Tablets should be prescribed.

Warning and precautions

Talk to your doctor or pharmacist before taking Doxycycline 100mg Tablets:

- If 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.
- If you have kidney or liver problems.
- If you have myasthenia gravis (a disease which causes unusual tiredness and weakness of certain muscles, particularly in the eyelids).
- If you have an immune system disease that causes joint pain, skin rashes and fever (systemic lupus erythematosus). The condition may be worsened by taking Doxycycline 100mg Tablets.
- If you have porphyria (a rare disease of blood pigments).
- If 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 100mg Tablets.
- 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 100mg Tablets 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.
- If 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 100mg Tablets.

When used for a long duration, Doxycycline 100mg Tablets 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 100mg Tablets

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

- Antacids (indigestion remedies), iron preparations, oral zinc or bismuth.

These should not be taken at the same time of day as Doxycycline Tablets.

- Carbamazepine, phenytoin (medicines used to control epilepsy) and barbiturates (used to control epilepsy or as a sedative).

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

- Increased action of warfarin or coumarins (used to prevent blood clots)
- Reduced effectiveness of oral contraceptives (birth control pills)
- Reduced effectiveness of penicillin antibiotics (used to treat infections)
- Increased blood levels of ciclosporin (a medicine used to affect the body's immune response).

If you are going to have a general anaesthetic for an operation or dental surgery you must tell your anaesthetist or dentist that you are taking doxycycline as you may have more side effects.

Taking Doxycycline 100mg Tablets with food, drink and alcohol

Please see section 3 How to take Doxycycline 100mg Tablets. Alcohol may reduce the effect of Doxycycline 100mg Tablets and should be avoided.

Pregnancy and breast-feeding

Doxycycline 100mg Tablets must not be taken if you are pregnant or breast-feeding. 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

Taking these tablets should not affect your ability to drive or operate machinery, however, if you think that you are affected you should not drive or operate machines until you feel better.

3. HOW TO TAKE DOXYCYCLINE 100MG TABLETS

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

Swallow the tablets whole with a glass of water. If the tablets irritate your stomach take them with food or milk. You should take the tablets either sitting down or standing up and well before you go to bed for the night to stop irritation and ulceration of your gullet (food pipe). It is important not to lie down for at least thirty minutes after taking Doxycycline 100mg Tablets, so that the tablet 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 100mg Tablets can be taken with or without food. For the treatment of acne, it is recommended to take Doxycycline 100mg Tablets with food or a drink.

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)

2 tablets on the first day, then 1 tablet daily. The length of treatment is dependent on the infection being treated.

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:

200mg on the first day (taken as a single dose or divided into two equal doses with a twelve hour interval), then 100 mg daily. The length of treatment is dependent on the infection being treated.

Specific infections:

- Acne vulgaris - 50mg a day with food or fluid for 6-12 weeks.
- Sexually transmitted disease - 100mg twice a day for 7-10 days.
- Primary and Secondary syphilis- 300mg a day in divided doses for 10 days.
- Fever caused by lice or ticks - a single dose of 100-200mg depending upon severity of infection.
- Malaria, when chloroquine is not effective - 200mg a day for at least 7 days, should be given with other drugs such as quinine.
- Prevent infections with scrub typhus - 200mg as a single dose.
- Prevent travellers' diarrhoea - 200mg on the first day of travel followed by 100mg a day throughout the duration of the stay. Do not use for more than 3 weeks unless advised by your doctor.
- Prevent leptospirosis infections - 200mg once a week throughout the stay in the infected area and 200mg at the end of the trip. Do not use for more than 3 weeks unless advised by your doctor.
- Prevent malaria - 100mg daily. Treatment should begin 1-2 days before travelling and continue daily whilst travelling. On leaving the malaria infected area, treatment should be continued for a further 4 weeks.

You should start to feel better within a few days. If you have been given Doxycycline 100mg Tablets 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.

ALWAYS follow the dosage given to you by your doctor.

If you have any concerns about the dose to take you should contact your doctor or pharmacist.

If you take more Doxycycline 100mg Tablets than you should

This medicine is to be taken at regular intervals, as determined by the doctor. If you take too many tablets by mistake contact your nearest hospital casualty department or tell your doctor immediately. Take your tablet pack with you.

If you forget to take Doxycycline 100mg Tablets

If you forget to take a tablet take it as soon as you can. Take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose. If you have trouble remembering to take the tablets, tell your doctor or pharmacist.

If you stop taking Doxycycline 100mg Tablets

If you stop taking the tablets too soon, the infection may return. Take the tablets for the full time of treatment, even when you begin to feel better.

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.

Stop taking the tablets immediately and seek urgent medical advice if:

- you experience sudden wheeziness, difficulty in breathing, chest pain, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- you experience 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.
- you experience 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.
- you experience 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. The possible symptoms in benign intracranial hypertension include headache, vomiting, visual disturbances including blurred vision, a localized defect in the visual field bordered by an area of normal vision (scotoma), double vision (diplopia), and possible vision loss, in some cases, even permanent.
- you experience serious illness with widespread severe blistering of the skin, mouth, eyes and genitals.

Contact your doctor at once if the following reactions happen:

- 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.

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 erythematosus (SLE). This is an allergic condition which causes joint pain, skin rash and fever, 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.
- 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
- 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).

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, 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 DOXYCYCLINE 100MG TABLETS

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 label and carton. The expiry date refers to the last day of that month.

Store in a cool dry place and protect from light. Do not use this medicine if you notice any visible signs of deterioration.

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 Doxycycline 100mg Tablets contain

The active substance is doxycycline. Each tablet contains 100mg of doxycycline.

The other ingredients are furcellaran, povidone, magnesium stearate, colloidal silicon dioxide, stearic acid, talc, microcrystalline cellulose, hypromellose, dimethicone, propylene glycol, titanium dioxide, industrial methylated spirit and hydroxypropylmethylcellulose (E464).

What Doxycycline 100mg Tablets look like and contents of the pack

Doxycycline 100mg Tablets are pink, round, film-coated tablets with P1 marked on one side and breakline on the other side.

Doxycycline 100mg Tablets are available in securitainers containing 10 or 50 tablets.

Not all pack sizes may be marketed.

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