Package leaflet: Information for the user

Doxat 100 mg Film-coated tablets
Doxycycline

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

1. What Doxat is and what it is used for

Doxat contains the active substance doxycycline as doxycycline hyclate. Doxat is an antibiotic belonging to a group of medicines called tetracyclines. It is used to treat many different types 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
- Acne (a skin condition)
- Eye infections
- Sexually transmitted diseases e.g. gonorrhoea, syphilis, chlamydia
- Fevers associated with louse or tick bites
- Malaria, when chloroquine is not effective

Doxat is also 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 Doxat to treat another infection not listed above. You may also be prescribed an additional medicine to take with Doxat 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 Doxat

Do not take Doxat:

- 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 Doxat 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).

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 Doxat should be prescribed.

Warnings and precautions

Talk to your doctor or pharmacist before taking Doxat 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 Doxat.
- 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 Doxat **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 Doxat.

When used for a long duration, Doxat 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 Doxat

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 Doxat.

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

- Antacids (indigestion remedies), iron preparations, oral zinc or bismuth. These should not be taken at the same time of day as Doxat.
- Carbamazepine, phenytoin (medicines used to control epilepsy) and barbiturates (used to control epilepsy or as a sedative).

Doxat 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.

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

Pregnancy and 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.
Doxat 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.

Doxat contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Doxat

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

- It is best to take your tablets 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 Doxat 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, Doxat can be taken with or without food.
- For the treatment of acne, it is recommended to take Doxat with food or a drink.
- If Doxat upsets 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)
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
200 mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.

Acne
Half a tablet daily for 6-12 weeks, with food or a drink.

Sexually Transmitted Diseases
1 tablet twice daily for 7 - 10 days.

Primary and Secondary Syphilis
2 tablets 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 one or two tablets depending on severity.

Treatment of malaria, when chloroquine is not effective
2 tablets daily for at least 7 days.

Prevention of malaria
1 tablet daily from 1-2 days before travelling to a malarial area until 4 weeks after returning.

Prevention of scrub typhus
Single dose of 2 tablets.

Prevention of travellers' diarrhoea
1 tablet twice daily on the first day of travel, followed by 1 tablet daily throughout the stay in the area. If you are planning to take these tablets for more than 21 days, please consult your doctor.

Prevention of leptospirosis
2 tablets once each week during the stay in the area; 2 tablets on completion of the trip. If you are planning to take these tablets for more than 21 days, please consult your doctor.

You should start to feel better within a few days. If you have been given Doxat 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.

Treatment of 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.

If you take more Doxat than you should
If you take too much Doxat contact your doctor or nearest hospital immediately. Always take the labelled medicine package with you, whether there is any Doxat left or not.

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

If you stop taking Doxat

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 may cause side effects although not everybody gets them.

Stop taking this medicine and tell your doctor immediately if you experience any of the following serious 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.
- 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 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.

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

- 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 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.

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 feverheadache.
- 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

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Medicines Authority, Post-Licensing Directorate, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwan SĠN 3000, E-mail: postlicensing.medicinesauthority@gov.mt or via the Malta ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Doxat

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

Store below 25ºC. Protect from light and humidity.

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

6. Contents of the pack and other information

What Doxat contains

- The active substance is doxycycline. Each film-coated tablet contains 100 mg doxycycline as hyclate.
- The other ingredients are: magnesium stearate, colloidal silicon dioxide, polyethylene glycol 6000, povidone, lactose, sodium starch glycolate, microcrystalline cellulose.
  Film-coating: hydroxypropylmethyl cellulose, polyethylene glycol 400, titanium dioxide and riboflavine.

What Doxat looks like and contents of the pack

Doxat film-coated tablets are yellow, oblong, film-coated tablets scored on both sides.
Doxat film-coated tablets are supplied in blister packs consisting of 1x10 tablets.

Marketing Authorisation Holder and Manufacturer

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