

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vibramycin-D 100 mg Dispersible tablets

Doxycycline

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Vibramycin-D is and what it is used for
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1. What Vibramycin-D is and what is it used for

Vibramycin-D 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.

Vibramycin-D is 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 Vibramycin-D to treat another infection not listed above. You may also be prescribed an additional medicine to take with Vibramycin-D to treat your infection. If you have any questions talk to your doctor.

2. Before you take Vibramycin-D

Do not take Vibramycin-D if:

- you are allergic (hypersensitive) to doxycycline or any other tetracycline antibiotic or any of the other ingredients listed in section 6.
- you are pregnant or trying to become pregnant.
- you are breast feeding.
- the medicine has been prescribed for a child under the age of 12 years.

You should not use Vibramycin-D during periods of tooth development (pregnancy, infancy or in children below 12 years old) as such use may lead to permanent discolouration (yellow-grey-brown) or affect the proper growth of the teeth.

Take special care with Vibramycin-D:

You should tell your doctor before you take Vibramycin-D 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 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 Vibramycin.
- you are suspected as having syphilis. Your doctor will continue to monitor you after your treatment has stopped.

Taking other medicines

If you are taking any of the medicines listed below tell your doctor before taking Vibramycin-D.

Some medicines can reduce the effectiveness of Vibramycin-D, these include:

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

Vibramycin-D 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.

You should tell your doctor if you are taking or have recently taken any other medicines including those obtained without a prescription.

Taking Vibramycin-D with food or drink

For the treatment of infections, Vibramycin-D can be taken with or without food.

For the treatment of acne, it is recommended to take Vibramycin D with food or a drink.

If Vibramycin-D upsets your stomach then taking it with food or milk is recommended.

Alcohol may reduce the effect of Vibramycin-D and should be avoided.

Pregnancy and breast-feeding

Vibramycin-D 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 Vibramycin-D

- Take Vibramycin-D tablets by letting the tablet break up in a small amount of water. Do not swallow the tablet without letting it break up in water first.
- 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 Vibramycin-D 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).
- If your stomach is upset Vibramycin-D can be taken with food or milk.

The list below shows the different doses that your doctor may prescribe depending on the infection being treated. Always take Vibramycin-D exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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.

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 Vibramycin-D 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.

If you take more Vibramycin-D than you should

If you take too much Vibramycin-D contact your doctor or nearest hospital Casualty Department immediately. Always take the labelled medicine package with you, whether there is any Vibramycin-D left or not.

If you forget to take Vibramycin-D

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 Vibramycin-D

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 about the use of this product, ask your doctor or pharmacist for advice.

YOU WILL FIND MORE ABOUT VIBRAMYCIN-D ON THE BACK OF THIS LEAFLET

4. Possible side effects

Like all medicines Vibramycin-D may cause some side effects but not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms of an allergic reaction after taking this medicine. Although they are very rare, the symptoms can be severe.

- Sudden wheeziness, difficulty in breathing, chest pain, fever, sudden swellings, rash or itching (especially affecting the whole body).

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

- Skin rash, or flaking or peeling of the skin.
- Severe skin reactions which may cause you to feel very unwell.
- 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.
- Very severe headache which may be associated with visual disturbance such as blurred vision or loss of vision.
- 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.

The side effects listed below are infrequent. These 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:

- upset stomach, loss of appetite, diarrhoea (this, may occur up to two or three months after the last dose), stomach pain, heartburn, feeling or being sick
- 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.

The following side effects have also been reported:

- Worsening of a disease called systemic lupus erythematosus (SLE). This is an allergic condition which causes joint pain, skin rash and fever.
- Inflammation of the bowel.
- Bulging fontanelles (soft spot on head) of infants.
- Inflammation and damage to the liver, yellow skin and eyes (jaundice), inflammation of the pancreas and abnormal liver function tests.
- Increased levels of urea in the blood.
- Pericarditis (inflammation affecting the heart).
- Discolouration and/or lack of growth of teeth.
- 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.

If any of these side effects get serious, or you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Vibramycin-D

Keep all medicines out of the reach and sight of children.

Keep your medicine below 25°C.

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

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. Further information

What Vibramycin-D contains

The active substance in the dispersible tablets is doxycycline (100 mg).

The other ingredients are: anhydrous colloidal silica, magnesium stearate and microcrystalline cellulose.

What Vibramycin-D looks like and contents of the pack

Vibramycin-D Dispersible tablets are light yellow round tablets scored on one side and marked VN on the other side.

Vibramycin-D Dispersible tablets come in blister packs of 8.

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June 2010

Ref: VM9_1

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