

Package leaflet: Information for the user
Vibramycin™ Capsules 100 mg
Doxycycline (as 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 Vibramycin is and what it is used for
2. What you need to know before you take Vibramycin
3. How to take Vibramycin
4. Possible side effects
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1. What Vibramycin is and what it is used for

This medicine contains doxycycline, which 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.
- Eye infections.
- Sexually transmitted diseases e.g. gonorrhoea, syphilis, chlamydia.
- Fevers associated with louse or tick bites.
- Malaria, when chloroquine is not effective.

Vibramycin 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, cholera and leptospirosis (a bacterial infection from contaminated water).

Your doctor may want you to take Vibramycin to treat another infection not listed above. You may also be prescribed an additional medicine to take with Vibramycin to treat your infection. You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Vibramycin

Do not take Vibramycin:

- if you are allergic (hypersensitive) 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.
- if you suffer from a condition where you have difficulties when swallowing.

You should not use Vibramycin 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 Vibramycin should be prescribed.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vibramycin:

- 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.
- you have myasthenia gravis (a disease which causes unusual tiredness and weakness of certain muscles, particularly in the eyelid).
- 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 Vibramycin.
- if you are suspected of 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 Vibramycin **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 suffer from acid reflux. Vibramycin may make your condition worse and may not be a suitable medicine for you.
- if you suffer from problems with the pancreas.
- if you experience increased pressure in your skull (severe headache) with changes in vision.

Tell your doctor straight away if you get serious skin reactions when taking this medicine, such as skin rash with blistering or peeling, mouth or genital ulcers often with flu-like symptoms (these may be signs of Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) or Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)).

If you start to have difficulties when swallowing or feel discomfort in your throat or stomach after taking Vibramycin tell your doctor immediately. Your doctor may advise you to stop taking Vibramycin.

When used for a long duration, Vibramycin 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 Vibramycin

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).

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

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

Vibramycin 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).
- Methoxyflurane (a type of anaesthetic).

Having an operation or dental surgery

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 Vibramycin as you may have more side effects.

Laboratory Tests

Vibramycin may interfere with some tests, tell your doctor if you need to give samples for laboratory assessment.

Pregnancy and breast-feeding

Do not take Vibramycin if you are pregnant, trying to become pregnant or breast-feeding (see section 2).

Driving and using machines

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

Vibramycin contains lactose monohydrate

Vibramycin capsules contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Vibramycin.

Vibramycin contains sodium

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

3. How to take Vibramycin

- Take Vibramycin capsules with a full glass of water when sitting or standing.
- It is best to take Vibramycin in the morning if possible, or at least 1 hour before going to bed.
- It is important not to lie down for at least thirty minutes after taking Vibramycin, 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).
- If your stomach is upset Vibramycin can be taken with food or milk.
- For the treatment of infections, Vibramycin can be taken with or without food.
- Alcohol may reduce the effect of Vibramycin and should be avoided.

The information below shows the different doses that your doctor may prescribe depending on the infection being treated. Doctors sometimes prescribe different doses to these. The label on the pack will tell you what dose YOU should take. Always take Vibramycin exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Usual Dose

2 capsules on the first day, then 1 capsule daily. For more severe infections 2 capsules daily should be given for the treatment period. 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; 200mg 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, then 100 mg daily. The length of treatment is dependent on the infection being treated.

Sexually transmitted diseases

1 capsule twice daily for 7 to 10 days.

Primary and Secondary Syphilis

1 capsule twice daily for 14 days. Your doctor will continue to monitor you after your treatment has stopped.

Fevers associated with louse or tick bites

Single dose of 1 or 2 capsules.

Treatment of malaria

2 capsules daily for at least 7 days. Your doctor will also prescribe you another medicine for malarial treatment (e.g. quinine) to be taken at the same time as Vibramycin.

Prevention of malaria

1 capsule daily from 1 to 2 days before travelling to a malarial area until 4 weeks after returning.

Prevention of scrub typhus (a disease carried by small insects)

Single dose of 2 capsules, once a week.

Prevention of travellers' diarrhoea

2 capsules on the first day of travel, followed by 1 capsule daily throughout the stay in the area. If you are planning to take Vibramycin for more than 21 days, please consult your doctor.

Treatment of leptospirosis (infections from contaminated water)

1 capsule twice daily for 7 days.

Prevention of leptospirosis (infections from contaminated water)

2 capsules once each week throughout the stay in the infected area; 2 capsules on completion of the trip. If you are planning to take Vibramycin for more than 21 days, please consult your doctor.

Treatment and prevention of cholera

A single dose of 3 capsules.

Stage 1 and 2 Lyme disease

1 capsule twice daily for 10 to 30 days. The length of treatment depends on how well you respond.

Infections due to susceptible strains of *Bacillus anthracis*

Adults: 1 capsule twice a day for 60 days.

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 Vibramycin than you should

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

If you forget to take Vibramycin

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 Vibramycin

If you stop taking the capsules too soon, the infection may return. Take the capsules 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.

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, tightness in chest, 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.
- Headache which, if very severe, may be associated with visual disturbance such as blurred vision or loss of vision. 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.

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 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.
- 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.

- 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 or diarrhoea.

The following side effects 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
- pericarditis (inflammation affecting the heart)

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

- heartburn

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

- inflammation of the pancreas which causes severe pain in the abdomen and back
- 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, blistering (hives), and itching, which usually recurs at the same site(s) on re-exposure to the medication (fixed drug eruption)
- darker patches on your skin
- loosening of the nail from the nail bed after exposure to the sun
- increased levels of urea in the blood

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

- yellow skin and eyes (jaundice), inflammation of the pancreas
- 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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vibramycin

Keep this medicine out of the sight and reach of children.
Keep your medicine below 25°C.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. 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 Vibramycin contains

The active substance is doxycycline (as hyclate). Each capsule contains 100 mg of doxycycline.

The other ingredients are: maize starch, lactose monohydrate, alginic acid, magnesium stearate, sodium laurilsulfate (see section 2 “Vibramycin contains Sodium”). The capsule shell contains: gelatin, titanium dioxide (E171), indigo carmine (E132) and yellow iron oxide (E172).

What Vibramycin looks like and contents of the pack

Vibramycin capsules are hard, dark green opaque capsules printed “Pfizer Vibracina” in off-white colour.

Vibramycin capsules come in blister packs of 12.

Marketing Authorisation Holder

Pfizer Healthcare Ireland Unlimited Company

The Watermarque Building

Ringsend Road, Dublin 4,

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Manufacturer

Farmasierra Manufacturing SL.

Carretera de Irún Km. 26.200

28700 San Sebastián de los Reyes

Madrid, Spain

Company contact address:

For further information on your medicine contact Medical Information at the following address:

Pfizer Healthcare Ireland Unlimited, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland. Telephone 1800 633 363

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