



VIBRAMYCIN

doxycycline monohydrate

100mg Tablets

Reference market: Switzerland

AfME Markets using same as LPLD:

PACKAGE LEAFLET



Patient Information Leaflet

Read this package leaflet carefully before using or taking this medicine.

This medicine has been prescribed personally for you only, and you must not pass it on to others. The medicine may harm them, even if their signs of illness are the same as yours.

Keep this package leaflet, you might want to read it again.

Vibramycin® Tabs

What is Vibramycin Tabs and what is it used for?

Vibramycin Tabs is an antibiotic in the tetracycline group which is used to treat infections caused by bacteria.

Vibramycin Tabs is used to treat infections such as

- Infections of the airways
- Ear, nose and throat infections
- Urinary tract infections
- Genital organ infections
- Infections of the skin and soft tissues
- Gastrointestinal infections
- Infections in obstetrics and gynaecology
- Infections of the mouth
- Eye infections
- Certain tick-borne infections.

Vibramycin Tabs is used as prophylaxis for the following infections:

- Traveller's diarrhoea
- Malaria in certain regions

Vibramycin Tabs may only be used on a doctor's prescription.



What should you consider?

Remember that this medicine has been prescribed by your doctor to treat your current illness. It may not be used to treat other diseases or other persons.

The antibiotic in Vibramycin Tabs is not effective against all micro-organisms that cause infections. Using an improperly selected or incorrectly dosed antibiotic can lead to complications. Therefore, never use it on your own initiative to treat other diseases or other persons. Do not use Vibramycin Tabs to treat subsequent new infections without a new doctor's prescription either.

When should Vibramycin Tabs not be taken?

If you are allergic to the active ingredient doxycycline, any of the other ingredients in Vibramycin Tabs or other tetracyclines, you must not use Vibramycin Tabs. Tell your doctor if you have ever had an allergic reaction to antibiotics with side effects or if you did not tolerate previous treatment with Vibramycin Tabs well.

Hypersensitivity manifests as shortness of breath (asthma), circulatory symptoms, swelling of the skin (e.g. hives) and mucous membranes, itching or skin rashes, among others.

Vibramycin Tabs must not be used in severe liver disease.

When should Vibramycin Tabs be taken with caution?

When tetracyclines are taken during the second half of pregnancy, in small children or in children up to 12 years of age, this can lead to persistent yellow-greyish-brown discolouration of the teeth or inadequate enamel development.

Vibramycin Tabs may therefore only be taken by these patients when expressly prescribed by a doctor.

If you suffer from liver damage, you should only take Vibramycin Tabs if your doctor has expressly prescribed them and you are under medical supervision.

If a skin reaction occurs (like skin rash or itching), you should stop taking the medicine and inform your doctor immediately.

As Vibramycin Tabs can cause photosensitivity reactions, you should avoid sunlight or sunlamps. If you develop skin redness when exposed to direct UV or sunlight, you should stop taking this medicine and immediately contact your doctor.

In order to reduce the risk of oesophageal irritation or ulcer, you should dissolve Vibramycin Tabs tablets in around 50 ml of water and take it with a lot of liquid.

Mild digestive troubles are possible when taking Vibramycin Tabs tablets. If you experience severe gastrointestinal disturbances with vomiting and diarrhoea, however, stop taking the medicine and inform your doctor immediately.

If you experience diarrhoea, do not take any medicines which inhibit peristalsis (bowel movement).

Patients who are taking antacids or bismuth salts for stomach problems or patients who are taking iron-containing products should not take these at the same time as Vibramycin Tabs as these medicines adversely affect the absorption of Vibramycin Tabs (i.e. its absorption into the bloodstream). This also applies for medical activated charcoal and cholestyramine-containing medicines. Vibramycin Tabs should therefore be taken either 2 hours before or 4 hours after these products.

Antibiotic combinations: another antibiotic may only be taken together with Vibramycin Tabs if expressly prescribed by a doctor.

Please inform your doctor if you are taking anticoagulants (medicines to thin the blood), oral anti-diabetics (medicines to decrease blood sugar), medicines to reduce epileptic seizures, sleep aids or oral contraceptives («the pill»).

If you are taking a contraceptive («the pill»), please note that its effectiveness may be decreased during antibiotic treatment. For this reason, your doctor or pharmacist may recommend other contraceptive measures.

Please tell your doctor if you are scheduled to undergo anaesthesia as concomitant use with a certain anaesthetic (methoxyflurane) may result in fatal kidney damage.

You should not consume alcohol during treatment with Vibramycin Tabs.

Concomitant use of doxycycline and ciclosporin A can increase the toxic effect of the immunosuppressant (ciclosporin A).

Concomitant use of theophylline and tetracyclines can increase the incidence of gastrointestinal side effects.

Tetracyclines including doxycycline can cause a benign increase in intracranial pressure which is normally reversible. However, cases of permanent loss of vision were reported as a consequence of this increase in intracranial pressure in patients receiving treatment with tetracyclines including doxycycline. Please tell your doctor immediately if you experience

visual disturbances during treatment.

It is known that the active ingredient isotretinoin, which is used to treat acne, can also cause increased intracranial pressure in rare cases. Therefore, concomitant use of isotretinoin and doxycycline should be avoided.

Concomitant use of methotrexate and doxycycline can increase the concentration of methotrexate.

Please inform your doctor if you perform home urine glucose tests.

This medicine can adversely affect your ability to react, drive and use machines or tools.

Please inform your doctor or pharmacist if you

- suffer from other diseases (e.g. liver disease),
- have allergies or
- take or externally use other medicines (including those you buy over-the-counter yourself!).

May Vibramycin Tabs be used during pregnancy or while breast-feeding?

If you are pregnant or want to have a baby, you should not take Vibramycin Tabs unless they are expressly prescribed by a doctor.

Do not breast-feed during treatment with Vibramycin Tabs.

How to use Vibramycin Tabs?

Vibramycin Tabs should be swallowed at least one hour before meals and at least one hour before going to bed with sufficient amounts of liquid, while seated or standing.

If you experience gastrointestinal problems when taking the medicine as suggested, it is recommend that you take Vibramycin Tabs together with food or a glass of milk.

You should always strictly comply with the dose and duration of treatment prescribed by your doctor in order to get the full benefit of Vibramycin Tabs. Symptoms of illness often disappear before the infection is fully cured. Do not stop your therapy for this reason, even if you feel better.

Unless otherwise prescribed by the doctor, the following dose recommendations apply:

Adults and adolescents weighing more than 50 kg: on day 1, 200 mg (two 100 mg tablets or one

200 mg tablet), swallowed whole with sufficient liquid or dissolved in around 50 ml water in a single dose. 100 mg (1 tablet) on the following days. In specific indications, the daily dose may be higher, according to the doctor's prescription.

Do not change the prescribed dose on your own regimen. If you think the effects of this medicine are too weak or too strong, speak to your doctor or pharmacist.

What are the possible side effects of Vibramycin Tabs?

The following side effects may occur while taking Vibramycin Tabs:

Common: Photosensitivity. Serious sunburn, with involvement of the nails (nail detachment and discolouration) in rare cases, may occur after exposure to sunlight or UV radiation (see section «When should Vibramycin Tabs be taken with caution? »). Nausea, vomiting, headache, rash, hypersensitivity reactions (including anaphylactic shock, swelling, rash, low blood pressure, laboured breathing and increased heart rate), pericarditis, swelling of the skin or mucous membranes (e.g. swelling of the eyelids, lips or tongue), worsening of symptoms of systemic lupus erythematosus (an autoimmune disease), delayed hypersensitivity reactions, swelling of the arms or legs.

At the first signs of a skin reaction, you should stop taking the medicine and inform your doctor immediately.

Uncommon: Digestive disorders, inflammation of the throat and oral mucosa, hoarseness, black hairy tongue, itching, coagulation disorders, blood in urine.

Rare: Pancreatitis (characterised by: suddenly occurring, strong pain in the upper abdomen, nausea and vomiting), diarrhoea (see section «When should Vibramycin Tabs be taken with caution? »), inflammation of the tongue, discolouration of permanent teeth, difficulty

swallowing, decreased appetite, increased intracranial pressure (possible signs include headache, dizziness, tiredness, visual disturbances (double vision)), palpitations, restlessness and anxiety, perception disturbances (e.g. tingling sensation, etc.), protrusion of the fontanelles in toddlers, facial redness, severe inflammatory skin reactions, symptoms of a Jarisch-Herxheimer reaction (possible symptoms are: high fever, headache, joint and muscular pain, nausea and skin rash), abdominal pain, inflammatory lesions in the anus and genitals,

oesophagitis, oesophageal ulcers (see section, «When should Vibramycin Tabs be taken with caution? »), disturbance or loss of smell and taste perception, which are only partially reversible in some cases, changes in blood count, liver dysfunction, hepatitis, hepatotoxicity, ringing in the ears, skin hyperpigmentation, joint pain, muscle pain, kidney damage.

Very rare: Seizures.

Mild intolerance reactions which occur, e.g. loss of appetite, difficulty swallowing, nausea, vomiting and diarrhoea, can usually be prevented by taking Vibramycin Tabs with a glass of milk, yoghurt or after a small meal.

Please inform your doctor immediately

- if you experience signs of a hypersensitivity reaction, e.g. itching, skin rash, swelling in the face, feeling of increased heartbeat, shortness of breath, swollen limbs;
- if you experience yellow discolouration of the skin or the whites of your eyes;
- if you get sudden stomach pain or vomiting, serious bloody or persistent diarrhoea;
- if you experience visual disturbances.

Inform your doctor or pharmacist if you get any side effects which are not listed here.

What else should be considered?

Do not use Vibramycin Tabs after the date which is stated on the container after «EXP».

Do not store Vibramycin Tabs above 30 °C. Vibramycin Tabs should be protected from light and humidity.

Keep out of the sight and reach of children.

After completing the treatment, take the package with the remaining medicine to your dispensing location (doctor or pharmacist) for them to destroy it.

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.



Your doctor or pharmacist will provide you with further information. These individuals have access to the detailed summary of product characteristics.

What is contained in Vibramycin Tabs?

1 scored Vibramycin Tab contains 100 or 200 mg doxycycline as its active ingredient and as its excipients: colloidal silicon dioxide, microcrystalline cellulose, carboxymethylcellulose sodium, magnesium stearate, colourants: E104, E132, E173.

Where to obtain Vibramycin Tabs? Which packages are available?

In pharmacies with a doctor's prescription, which allows only a one-time purchase.

Vibramycin Tabs, 100 mg (scored): packages of 8, 10 and 25 tablets.

Vibramycin Tabs, 200 mg (scored): packages of 8 tablets.

Not all pack sizes maybe marketed.

Market Authorisation Holder

PFIZER PFE SWITZERLAND GMBH, SCHÄRENMOOSSTRASSE 99, 8052 ZÜRICH
SWITZERLAND.

Manufacturer:

Fareva Amboise

Zone Industrielle

29 route des Industries

37530 Pocé-sur-Cisse

France

This package leaflet was last revised in July 2018.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

Council of Arab Health Ministers

Union of Arabic Pharmacists