

Package leaflet: Information for the patient**VIBRAMYCIN[®]**
(Doxycycline)

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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 use Vibramycin
3. How to use Vibramycin
4. Possible side effects
5. How to store Vibramycin
6. Contents of the pack and other information

1. What Vibramycin is and what it is used for**What Vibramycin is**

Vibramycin contains the active substance doxycycline as doxycycline hyclate. Vibramycin is an antibiotic belonging to a group of medicines called tetracyclines.

How Vibramycin works

Vibramycin is primarily bacteriostatic and is thought to exert its antimicrobial effect by the inhibition of protein synthesis. Doxycycline is active against a wide range of gram-positive and gram-negative microorganisms.

What Vibramycin is used for

Vibramycin is used for the treatment of many different types of infections including:

- Rocky Mountain spotted fever, typhus fever and the typhus group;
- Q fever, rickettsial pox and tick fevers caused by *Rickettsiae*;
- Respiratory infections caused by *Mycoplasma pneumoniae*;
- Psittacosis caused by *Chlamydia psittaci*;
- Lymphogranuloma venereum (ulcerative disease of the genital area), caused by *Chlamydia trachomatis*;
- Uncomplicated urethral, endocervical or rectal infections in adults caused by *Chlamydia trachomatis*;
- Trachoma (contagious bacterial eye infection) caused by *Chlamydia trachomatis*;
- Inclusion conjunctivitis (inflammation of the conjunctiva) caused by *Chlamydia trachomatis* may be treated with oral doxycycline alone or with a combination of topical agents;
- Acute epididymo-orchitis (swelling of the epididymis) caused by *Chlamydia trachomatis* or *Neisseria gonorrhoeae*;
- Granuloma inguinale (sexually transmitted disease) caused by *Calymmatobacterium granulomatis*;

- Early (Stage 1 and 2) Lyme disease (tick-borne illness) caused by *Borrelia burgdorferi*;
- Louse-borne relapsing fever caused by *Borrelia recurrentis*;
- Tick-borne relapsing fever caused by *Borrelia duttonii*;
- Non-gonococcal urethritis (NGU) caused by *Ureaplasma urealyticum (T-Mycoplasma)*;
- Upper respiratory tract infections caused by *Streptococcus pneumoniae*;
- Respiratory, skin and soft-tissue infections caused by *Staphylococcus aureus*;

VIBRAMYCIN[®] is also used for the treatment of infections caused by the following gram-negative microorganisms and gram-positive microorganisms.

When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of:

- Actinomycosis caused by *Actinomyces* species;
- Infections caused by *Clostridium* species;
- Syphilis (sexually transmitted disease) caused by *Treponema pallidum* and yaws (tropical infection of the skin, bones, and joints) caused by *Treponema pertenue*;
- Listeriosis caused by *Listeria monocytogenes*;
- Vincent's infection (acute necrotizing ulcerative gingivitis) caused by *Leptotrichia buccalis*;

VIBRAMYCIN[®] is also used for the treatment

- In acute intestinal amebiasis;
- In severe acne caused by *Acne vulgaris*;
- Malaria caused by *Plasmodium falciparum*;
- Leptospirosis (food-borne infection) caused by genus *Leptospira*;
- Cholera caused by *Vibrio cholerae*
- Scrub typhus caused by *Rickettsia tsutsugamushi*
- Traveler's diarrhea caused by enterotoxigenic *Escherichia coli*

2. What you need to know before you use Vibramycin

Do not use Vibramycin

- 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 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).

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 have any of the following:

- 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 drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome (hypersensitivity syndrome).
- you have benign intracranial hypertension (high pressure around the brain causes symptoms like vision changes and headaches).
- 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.
- 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.
- 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.

Other medicines and Vibramycin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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).
- The concurrent use of tetracyclines and methoxyflurane has been reported to result in fatal renal toxicity.

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)
- Alcohol may reduce the effect of Vibramycin 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 for advice before using this medicine.

Vibramycin must not be taken if you are pregnant or breast-feeding.

Driving and using machines

There is no evidence to suggest that Vibramycin may affect driving and using machines.

3. How to use Vibramycin

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.

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.

Tick- and louse-borne relapsing fevers and louse-borne typhus:

Single oral dose of 100 or 200 mg, according to severity. As an alternative to reduce the risk of relapse of tick-borne relapsing fever, doxycycline 100 mg every 12 hours for seven days is taken.

Early Lyme disease (Stage 1 and 2):

Vibramycin 100 mg orally twice daily for 14-60 days, according to clinical signs, symptoms and response.

Uncomplicated urethral, endocervical or rectal infection:

In adults: 100 mg, orally, twice daily for seven days.

Acute epididymo-orchitis:

Ceftriaxone 250 mg IM or other appropriate cephalosporin in a single dose, plus Vibramycin 100 mg orally twice daily for 10 days.

Non-gonococcal urethritis (NGU):

Vibramycin 100 mg, orally twice daily for seven days.

Lymphogranuloma venereum:

Vibramycin 100 mg orally twice daily for a minimum of 21 days.

Uncomplicated gonococcal infections of the cervix, rectum or urethra:

Vibramycin 100 mg orally twice daily for seven days plus co-treatment with an appropriate cephalosporin or quinolone is recommended, such as the following: Cefixime 400 mg orally in a single dose or Ceftriaxone 125 mg intramuscularly (IM) in a single dose or Ciprofloxacin 500 mg orally in a single dose or Ofloxacin 400 mg orally in a single dose.

Uncomplicated gonococcal infections of the pharynx:

Vibramycin 100 mg twice daily for seven days, plus co-treatment with an appropriate cephalosporin or quinolone is recommended, such as the following: Ceftriaxone 125 mg IM in a single dose or Ciprofloxacin 500 mg orally in a single dose or Ofloxacin 400 mg orally in a single dose.

Primary and secondary syphilis:

Vibramycin 100 mg orally twice daily for two weeks, as an alternative to penicillin therapy.

Latent and tertiary syphilis:

Vibramycin 100 mg orally twice daily for two weeks, as an alternative to penicillin therapy if the duration of the infection is known to have been less than one year. Otherwise, doxycycline should be administered for four weeks.

Acute pelvic inflammatory disease (PID):

Inpatient: Vibramycin 100 mg every 12 hours, plus cefoxitin 2 g IV every 6 hours or cefotetan 2 g IV every 12 hours for at least four days and at least 24 to 48 hours after patient improves. Then continue doxycycline 100 mg by mouth twice daily to complete 14 days total therapy.

Out-patient: Vibramycin 100 mg by mouth twice daily for 14 days as adjunctive therapy with Ceftriaxone 250 mg IM once or Cefoxitin 2 g IM, plus probenecid 1 g orally in a single dose concurrently once, or other parenteral third-generation cephalosporin (e.g., ceftizoxime or cefotaxime).

Acne vulgaris: 50-100 mg daily for up to 12 weeks.

For treatment of chloroquine-resistant falciparum malaria: 200 mg daily for at least seven days. Due to the potential severity of the infection, a rapid-acting schizonticide such as quinine should always be given in conjunction with doxycycline; quinine dosage recommendations vary in different areas.

For prophylaxis of malaria: 100 mg daily in adults; for children over 8 years of age the dose is 2 mg/kg given once daily up to the adult dose. Prophylaxis can begin 1-2 days before travel to malarious areas. It should be continued daily during travel in the malarious areas and for four weeks after the traveler leaves the malarious area.

For the treatment and selective prophylaxis of cholera in adults: 300 mg in a single dose.

For the prevention of scrub typhus: 200 mg as a single oral dose.

For the prevention of traveler's diarrhea in adults: 200 mg on the first day of travel (administered as a single dose or as 100 mg every 12 hours) followed by 100 mg daily throughout the stay in the area. Data on the use of the drug prophylactically are not available beyond 21 days.

For the prevention of Leptospirosis: 200 mg orally on a weekly basis throughout the stay in the area and 200 mg at the completion of the trip. Data on the use of the drug prophylactically are not available beyond 21 days.

For the treatment of Leptospirosis: 100 mg orally twice daily for seven days.

Inhalational anthrax (post-exposure):

ADULTS: 100 mg of doxycycline, orally twice a day for 60 days.

CHILDREN: weighing less than 45 kg; 2.2 mg/kg of body weight, by mouth, twice a day for 60 days. Children weighing 45 kg or more should receive the adult dose.

Rocky Mountain spotted fever:

Doxycycline is the first line treatment for adults and children of all ages:

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 is reduced and until there is health improvement. Minimum course of treatment is 5-7 days.

Capsules and film-coated tablets are taken with adequate amounts of fluid in the tetracycline to reduce the risk of esophageal irritation and ulceration. If Vibramycin upsets your stomach then taking it with food or milk is recommended.

If you take more Vibramycin than you should

If you take too much Vibramycin contact your doctor or nearest hospital 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 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

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. Some of these effects may be serious.

- **Blood and lymphatic system disorders:** Haemolytic anaemia, neutropenia (low WBC), thrombocytopenia (low platelets), eosinophilia (high levels of certain white blood cells).
- **Immune system disorders:** Hypersensitivity (including anaphylactic shock, anaphylactic reaction, anaphylactoid reaction, angioedema, exacerbation of systemic lupus erythematosus, pericarditis, serum sickness, Henoch-Schonlein purpura (inflammation and bleeding in the small blood vessels), hypotension, dyspnoea, tachycardia, peripheral oedema and urticaria), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Jarisch-Herxheimer reaction.
- **Endocrine disorders:** Brown-black microscopic discolouration of thyroid glands.
- **Metabolism and nutrition disorders:** Decreased appetite.

- **Nervous system disorders:** Benign intracranial hypertension (pseudotumor cerebri), fontanelle bulging (brain swells), headache.
- **Ear and labyrinth disorders:** Tinnitus (ringing or buzzing noise in your ears).
- **Vascular disorders:** Flushing (reddening of the skin).
- **Gastrointestinal disorders:** Pancreatitis, pseudomembranous colitis, *Clostridium difficile* colitis, oesophageal ulcer, oesophagitis, enterocolitis, inflammatory lesions (with monilial overgrowth) in the anogenital region, dysphagia, abdominal pain, diarrhoea, nausea/vomiting, dyspepsia (heartburn/gastritis), glossitis, tooth discolouration.
- **Hepatobiliary disorders:** Hepatotoxicity, hepatitis, hepatic function abnormal.
- **Skin and subcutaneous tissue disorders:** Toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme, dermatitis exfoliative, photosensitivity reaction, skin hyperpigmentation, photoonycholysis (separation of the nail plate from the nail bed), rash including maculopapular and erythematous rashes.
- **Musculoskeletal and connective tissue disorders:** Arthralgia (joint pain), myalgia (muscle pain).
- **Renal and urinary disorders:** Blood urea increased.

5. How to store Vibramycin

Store at controlled room temperature 15°C-30°C.
Avoid exposure to heat, sunlight and moisture.

6. Contents of the pack and other information

What Vibramycin contains

Vibramycin is available as:

Capsules containing 100 mg of doxycycline as the hyclate salt.

Film-coated tablets containing 100 mg of doxycycline as the hyclate salt.

What Vibramycin looks like and contents of the pack

Vibramycin 100 mg capsules are available in the pack of 120s.

Vibramycin 100 mg tablets are available in the pack of 30s.

Vibramycin/PIL/PK-01

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