VIBRAMYCIN® TABLET

Doxycycline Hydrochloride (100 mg)

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What VIBRAMYCIN is used for

VIBRAMYCIN is an antibiotic. It is used to treat many bacterial infections such as:

- Fever associated with louse or tick bites (typhus fever)
- Chest, lung or nasal infections e.g. pneumonia
- Sexually transmitted diseases e.g. gonorrhoea, syphilis, chlamydia
- Urinary tract infections (the passage through which urine passes) e.g. urethritis

It is also used for the prevention and treatment of malaria (when chloroquine is not effective), leptospirosis (a bacteria carried by animals and found in soil and water), and cholera.

It is used with other medicines to treat acne and intestinal parasites. It is also used to prevent scrub typhus and traveler's diarrhea.

How VIBRAMYCIN works

VIBRAMYCIN kills or prevents bacteria from growing.

Before you use VIBRAMYCIN

- *When you must not use it*

Do not use VIBRAMYCIN if you are allergic to doxycycline or any of its other ingredients or any other tetracycline.

Pregnancy and lactation

Do not take VIBRAMYCIN if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take VIBRAMYCIN if you are breast-feeding. Doxycycline is present in the milk of breastfeeding women. Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start to use it*

Tell your doctor if

- you are in the last half of pregnancy or the medicine has been prescribed for a child under the age of 8 years as it may cause permanent discolouration of teeth (yellow-gray-brown).
- you have diarrhoea or usually get diarrhoea when you take antibiotics. If you develop severe diarrhoea during or after using VIBRAMYCIN tell your doctor immediately since it may be necessary to stop the treatment.
- you are suspected to have syphilis.

The use of doxycycline might increase the incidence of vaginal candidiasis. Please consult with your doctor for further information.

If you take VIBRAMYCIN for a long time, your treating doctor may do some tests periodically.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.
VIBRAMYCIN should not be taken with the following:

- warfarin and other medicines used to prevent blood clot
- penicillin antibiotics
- antacids or any products that contain aluminum, calcium, magnesium, iron or bismuth salts. The absorption of tetracyclines is reduced when taking bismuth subsalicylate.
- medicines used to treat seizures (e.g. barbiturates, carbamazepine, phenytoin)
- rifampicin
- methoxyflurane, an anaesthetic
- alcohol
- oral contraceptives (birth control pill)
- isotretinoin (used to treat various skin conditions)

How to use VIBRAMYCIN

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dosage for adult is:

First day	200 mg/day as a single dose; or 100 mg every 12 hours
Following days	100 mg/day; or 50 mg every 12 hours

For more serious infections, 200 mg per day should be given throughout the treatment period.

For children of age 8 years or less, VIBRAMYCIN should only be given if the potential benefits of medicines are more than its side effects in the case for severe or life- threatening diseases such as Rocky mountain spotted fever (caused by ticks).

The recommended dosage for children above 8 years weighing 45 kg or less is:

First day	4.4 mg/kg per day; or 2.2 mg/kg every 12 hours
Following days	2.2 mg/kg per day; or 1.1 mg/kg every 12 hours

For children weighing more than 45 kg, the usual adult dose should be

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used.

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

Treatment of malaria: 200 mg daily for at least 7 days.

Prevention 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. Prevention 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 leaving the malarious area.

Treatment and selective prevention of cholera in adults: 300 mg in a single dose.

Prevention of scrub typhus: 200 mg as a single oral dose.

- *When to use it*

Use as directed by your doctor or pharmacist.

It is recommended that VIBRAMYCIN should be taken with food or milk.

If you are still having inflammation or ulcers of esophagus (food pipe), you can take the medications immediately before going to bed.

Take plenty of fluids with VIBRAMYCIN to reduce the risk of irritation and ulceration of the oesophagus.

- *How long to use it*

Continue taking VIBRAMYCIN for as long as your doctor recommends. Therapy should be continued at least 24 to 48 hours after symptoms and fever have subsided.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

In case of overdosage, discontinue medication.

While you are using it

- *Things you must do*

Tell all the doctors, dentists and pharmacists treating you that you are taking VIBRAMYCIN.

Tell your doctor immediately if you become pregnant while taking this medication.

VIBRAMYCIN Tablet may interfere with results of the fluorescence test.

Avoid excessive sunlight or artificial ultraviolet light and to discontinue therapy if phototoxicity (e.g., skin eruption, etc.) occurs. Sunscreen or sunblock should be considered.

Visit your doctor if you experience severe skin reactions, as your doctor may suggest you to stop VIBRAMYCIN immediately.

Drink fluids liberally along with doxycycline to reduce the risk of esophageal irritation and ulceration.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give VIBRAMYCIN to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines
The effect of VIBRAMYCIN on the ability to drive or operate heavy machinery has not been studied. There is no evidence to suggest that VIBRAMYCIN may affect these abilities.

Side effects

Like all medicines, VIBRAMYCIN can cause side effects, although not everybody gets them.

Some people have experienced the following side effects while taking VIBRAMYCIN:

Common (may affect greater than or equal to 1 in 100 people)
- Sensitivity to light
- Severe allergic reactions including
    - swelling
    - exacerbation of systemic lupus erythematosus (an autoimmune disease)
    - pericarditis (inflammation of the sac surrounding the heart)
    - Henoch-Schonlein purpura (condition which causes rash, abdominal pain and joint pains)
    - low blood pressure
    - shortness of breath
    - rapid heart rate and hives
- Headache
- Nausea/vomiting
- Rash

VIBRAMYCIN Tablet may cause Jarisch-Herxheimer reaction which usually consists of fever, chills, headache, muscle pain and skin rash. The reactions occur shortly after starting VIBRAMYCIN Tablet for spirochete infections and is often self-limiting.

If you experience any of the following, stop taking your medicine and contact your doctor immediately:
- vaginal thrush - sore and itchy vagina and/or discharge

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- increased pressure in the brain (headache, blurred vision, vomiting) severe diarrhoea, stomach cramps
- more frequent bruising than normal
- yellowing of the skin or eyes, pale stools, dark urine (jaundice)
- severe skin reactions such as erythema multiforme (circular, irregular red patches), Stevens-Johnson syndrome (rash with flushing, fever, blisters or ulcers), toxic epidermal necrolysis (reddening, peeling and swelling that resembles burns), drug induced skin rashes

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of VIBRAMYCIN

- *Storage*

  Keep out of the reach and sight of children.

  Store below 30°C.

- *Disposal*

  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.

Product Description

- *What it looks like*

  Vibramycin (China)
  VIBRAMYCIN film-coated tablet is a smooth, well formed, round biconvex, white to grey film-coated tablet.

  Packs of 100's (blister)

- *Ingredients*
  - Active ingredient
    Film-coated tablets containing 100 mg of doxycycline as the hyclate salt

  - Inactive ingredients
    Vibramycin (China)
    Lactose, Carmellose Calcium, Corn Starch, Hydroxypropylcellulose, Magnesium Stearate, Hydroxypropylmethylcellulose 2910, Macrogol 6000, Titanium Oxide, Liquid Paraffin, Talc, Carnauba Wax, White Beeswax, Isopropanol and Ethanol.

- *MAL number*

Product Name	**Registration Number**
Vibramycin 100 mg tablets (China)	MAL19860578AZ

Manufacturer
Manufactured by:
Viatris Pharmaceuticals (Dalian) Co. Ltd.,
Dalian, China

Packaged by:
Pfizer Global Supply Japan Inc.
Aichi, Japan

Product Registration Holder
Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11,
Wisma Averis, Tower 2,
Avenue 5, Bangsar South,
No. 8 Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

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