

PHARMANIAGA METRONIDAZOLE TABLET

Metronidazole (200mg, 400mg)

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What Pharmaniaga Metronidazole Tablet is used for

It is used to treat certain infections caused by bacteria and other organisms in different parts of the body.

It is also used to prevent or treat certain infections that may occur during surgery.

How Pharmaniaga Metronidazole Tablet works

Pharmaniaga Metronidazole Tablet is an antibiotic that belongs to a group of medicines called nitroimidazoles.

This medicine works by killing or stopping the growth of bacteria and other organisms causing these infections.

Before you use Pharmaniaga Metronidazole Tablet

-When you must not use it

Do not use Pharmaniaga Metronidazole Tablet if you have ever had an allergic reaction to:

- Pharmaniaga Metronidazole Tablet or any other nitroimidazoles derivation

- Trichomoniasis - Individuals having Sexually Transmitted Disease (STD)
- Or individuals having a first trimester of pregnancy

Pregnancy and Lactation

Do not take Pharmaniaga Metronidazole Tablet if you are pregnant, trying to get pregnant or think you may be pregnant without discussing with your doctor first.

Do not take Pharmaniaga Metronidazole Tablet if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Tell your doctor if you have or have ever had any health problems/ medical conditions including:

- A blood disorder.
- Disease of the brain, spinal cord or nerves.
- Liver or kidney disease.
- An inflammatory disease of the small intestine (e.g. Crohn's disease)
- You drink alcohol (Do not drink alcohol during and for 24 hours after stopping treatment with Pharmaniaga Metronidazole Tablet.
- You plan to become pregnant or breastfeed.

-Taking other medicines

Tell your doctor or pharmacist before taking Pharmaniaga Metronidazole Tablet, if you are taking any other medicines, including any that you buy without a prescription from pharmacy, supermarket or health food shop. The effects of some medicines may be affected if other medicines are used at the same time.

Some medicines may be affected by Pharmaniaga Metronidazole Tablet or may affect how well it works. These include:

- Alcohol
- Warfarin or other medicines used to prevent blood clots.
- Disulfiram (a medicine used to treat chronic alcohol dependence).
- Phenytoin (a drug used to treat convulsions).
- Phenobarbitone (a medicine for convulsions or sedation).
- Cimetidine (a medicine used to treat gastric reflux and ulcers).
- Lithium (a medicine used to treat manic depressive illness and some other types of depression).

How to use Pharmaniaga Metronidazole Tablet

Always take the medicine exactly as your doctor or pharmacist has told you. Read the direction labels carefully. If you have any concerns about how to take this medicine, talk to your doctor or pharmacist.

- How much to use

Tablets are to be taken with or after food.

The dose will vary from individual to individual. Your doctor will decide the right dose for you.

Amoebiasis, Balantidiasis, Blastocystis hominis infection

Adults : 400 to 800 mg three times daily for 5-10 days.

Children : 35 to 50 mg per kg body-weight daily in divided doses.

Giardiasis

Adults : 2 g daily as a single dose for 3 successive days.

Children : 15 mg per kg body-weight daily in divided doses.

Trichomoniasis

Adults : Single 2 g dose or a 7 day course of 200 mg three times daily or 400 mg twice daily or 2 day course of 800 mg in the morning and 1.2 g in the evening.

Sexual partners should be treated concomitantly.

Children : 15 mg per kg body-weight daily in divided doses for 7 days.

Bacterial vaginosis

Adults : Single 2 g dose or 7 day course of 400 mg twice daily.

Acute necrotising ulcerative gingivitis, acute dental infections

200 mg three times daily for 3 days.

Anaerobic bacterial infections

Adults : Initial dose of 800 mg followed by 400 mg every 8 hours for 7 days.

Children : 7.5 mg per kg body-weight every 8 hours.

-When to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

Pharmaniaga Metronidazole Tablet is to be taken with or after food.

-How long to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

-If you forget to use it

Take the missed dose as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting unwanted side effects.

-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.

Single oral doses of metronidazole up to 15 g have been reported in suicide attempts and accidental overdoses. Symptoms reported include nausea, vomiting and ataxia.

Oral metronidazole has been studied as a radiation sensitizer in the treatment of malignant tumours. Neurotoxic effects, including seizures and peripheral neuropathy, have been reported after 5 to 7 days of doses of 6 to 10.4 g every other day.

While you are using Pharmaniaga Metronidazole Tablet

-Things you must do

Take the medication exactly as your doctor prescribed.

- Tell your doctor or pharmacist if you have allergies to Pharmaniaga Metronidazole Tablet.
- Tell your doctor or pharmacist what other prescription and non-prescription medicines that you are taking.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Pharmaniaga Metronidazole Tablet.
- Tell your doctor immediately if you become pregnant while taking this medication.
- The symptoms of your infection do not improve or become worse.

-Things you must not do

Do not give Pharmaniaga Metronidazole Tablet to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not drink alcohol or any alcoholic drinks while using Pharmaniaga Metronidazole Tablet and for at least one day after

finishing treatment. The use of alcohol may make you feel very sick, vomit, have stomach cramps, headaches and flushing.

If you do not use all of the medicine prescribed by your doctor, all of the bacteria / organisms causing your infection may not be killed. These bacteria / organisms may continue to grow and multiply so that your infection may not clear completely or may return.

-Things to be careful of

If you are pregnant, trying to get pregnant or are breast-feeding, you should not take Pharmaniaga Metronidazole Tablet without discussing it with your doctor first.

Side Effects

Like all medicines, Pharmaniaga Metronidazole Tablet can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. Ask your doctor or pharmacist to answer any questions you may have.

The following reactions have also been reported during treatment with Pharmaniaga Metronidazole Tablet.

- Oral thrush - furry tongue
- Nausea, which may be accompanied by headache, anorexia, and vomiting.
- Diarrhoea, abdominal cramping or constipation, strange taste in mouth.
- Dizziness, weakness, feeling of incoordination.
- Confusion, irritability, depression or sleeplessness.
- Skin rashes, flushing.
- Dry mouth, nasal congestion, dryness of the mouth (or vagina or vulva).
- Unusual urination patterns (e.g. darkened urine).
- Joint pain.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5549, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Pharmaniaga Metronidazole Tablet

-Storage

Keep all medicines out of sight and reach of children.

Do not take this medicine after the expiry date stamped on the pack.

Store below 30°C. Protect from light. Keep container tightly closed.

-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

Pharmaniaga Metronidazole Tablet 200mg

Yellow, round, biconvex, film-coated tablets with 'RMB' breakline on one side and plain on the other.

Pharmaniaga Metronidazole Tablet 400mg

Yellow, round, biconvex tablets with 'Pharmaniaga icon' on one side and plain on the other.

Ingredients

Pharmaniaga Metronidazole Tablet 200mg

Active ingredient(s):
Metronidazole 200mg

Inactive ingredients:

Corn Starch, Povidone 90F, Sodium Starch Glycolate, Quinoline Yellow Lake, Sunset Yellow Lake, Magnesium Stearate, Purified Water, Opadry II Yellow.

Pharmaniaga Metronidazole Tablet 400mg

Active ingredient(s):
Metronidazole 400mg

Inactive ingredients:

Cornstarch, Providone 90F, Quinoline Yellow Lake, Sunset Yellow Lake, Sodium Starch Glycolate, Magnesium Stearate, Purified Water.

-MAL Number(s)

Pharmaniaga Metronidazole Tablet 200mg

MAL19973683AZ

Pharmaniaga Metronidazole Tablet 400mg

MAL20000678AZ

Manufacturer

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Date of Revision

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