PHARMANIAGA CLARITHROMYCIN TABLET

Clarithromycin (250mg,500mg)

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What Pharmaniaga Clarithromycin Tablet is used for

It is used to treat infection caused by pathogens sensitive to Clarithromycin. Clarithromycin belongs to a group of medicines called macrolide antibiotics.

Pharmaniaga Clarithromycin Tablet are used to treat infections such as:

- Chest infections such as bronchitis and pneumonia
- Throat and sinus infections
- Mild to moderate skin and tissue infections, e.g. cellulites (formation of lumps and dimples in the skin), folliculitis (hair follicles become inflamed) or erysipelas (bacterial infection in the upper layer of the skin).

How Pharmaniaga Clarithromycin Tablet works

Pharmaniaga Clarithromycin Tablet exerts an effect called bacteriostatic which stops the growth of bacteria (bugs) which cause infections.

Before you use Pharmaniaga ClarithromycinTablet

-*When you must not use it*

Do not take Pharmaniaga Clarithromycin Tablets if you;

- know that you are allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in the tablets.
- are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine.
- are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride (for stomach problems) or pimozide (for mental health problems) as combining these drugs can sometimes cause serious disturbances in heart rhythm.
- have low levels of potassium in the blood (a condition known as hypokalaemia).
- have severe liver disease with kidney disease.
- have an irregular heart rhythm.

- *Before you start to use it*

Your doctor needs to know before you take Pharmaniaga Clarithromycin Tablet if you have or have had any of the following conditions:

- if you have any liver or kidney problems
- if you have, or are prone to, fungal infections (e.g. thrush)
- if you are pregnant or breast feeding

- *Taking other medicines*

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any of the following medicines as your dose may need to be changed or you may need to have regular tests performed:

- digoxin, quinidine or disopyramide (for heart problems)
- warfarin (for thinning the blood)
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy)
- theophylline (used in individuals with breathing difficulties such as asthma)
- omeprazole (for treatment of indigestion and gastric ulcers)
- methylprednisolone (a corticosteroid)
- ciclosporin, sirolimus and tacrolimus (immune suppressants)
- lincomycin (for treatment of severe bacterial infections in people who cannot use penicillin antibiotics)
- clindamycin (antibiotic useful for the treatment of a number of bacterial infections)
- zidovudine (is used along with other medications to treat human immunodeficiency virus (HIV) infection)
- alprazolam (for treatment of to treat anxiety disorders and panic disorder)
- midazolam (produce a calming effect on the brain and nerves)
- rifabutin (antibiotic used to treat tuberculosis)
- triazolam (for treatment of certain sleep problem (insomnia
- Domperidone (treatment for nausea and vomiting).

How to use Pharmaniaga Clarithromycin Tablet

- *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.

Adults:

Clarithromycin recommended dosage in adults is one 250 mg tablet every 12 hours.

In cases of severe infections, dosage can be increased up to 500 mg every 12 hours.

Administration must be continued, according to severity of infection, up to 6-14 days.

In individuals with kidney impairment with creatinine clearance less than 30 ml/min, the dosage should be reduced by one-half. (Dosage should not be continued beyond 14 days in these individuals).

If you have severe kidney problems your doctor may give you a different dose.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking Pharmaniaga Clarithromycin Tablet for as long as your doctor recommends.

- *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.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Pharmaniaga Clarithromycin Tablet.

Tell your doctor immediately if you became pregnant while taking this medicine.

- *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 Pharmaniaga Clarithromycin Tablet to anyone else, even if they have the same symptoms or condition as you.

Do not give these tablets to children under 12 years. Your doctor will prescribe another suitable medicine for your child.

- *Things to be careful of*

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or if you are breast-feeding, consult your doctor before taking Pharmaniaga Clarithromycin Tablet as the safety of Pharmaniaga Clarithromycin Tablet in pregnancy and breast-feeding is not known.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

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

If you suffer from any of the following at any time during your treatment STOP TAKING your tablets and contact your doctor immediately.

After oral administration of clarithromycin, some common side effects have been reported such as:

- Stomach and intestinal disturbances (nausea, vomiting, heartburns, abdominal pain and diarrhea)
- Headache
- Skin rashes
- Anxiety
- Behavioral changes
- Hallucinations
- Insomnia
- Hepatic dysfunction

Pharmaniaga Clarithromycin Tablet may cause severe allergy and serious skin reaction. Stop using Pharmaniaga Clarithromycin and seek medical assistance immediately if your experience

- Skin reddening, blisters, rash, fever, sore throat or eye irritation.

Rare but serious side effects

- Hepatic failure with fatal outcome.
- A low blood sugar (hypoglycaemia), occurred in patients taking hypoglycaemic agents of insulin.

For immunocompromised patients, the most common side effects include:

- Deafness
- Purpuric rash (purplish discoloration of the skin produced by small bleeding vessels near the surface)
- Inflammation in the pancreas (pancreatitis)

Consult your doctor immediately if you develop any of these problems or have any other unexpected or unusual symptoms. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pharmaniaga Clarithromycin Tablet

- *Storage*

Keep the medicines in a cool dry place where the temperature stays below 30°C. Protect from light. Do not store it or any other medicine in the bathroom, or near a sink, or on a window sill.

Do not use this medication after the expiry date which is printed on the product packaging. The expiry date refers to the last day of that month. Keep it where children cannot reach it.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

- *What it looks like*

Pharmaniaga Clarithromycin Tablet 250mg
Yellow, oblong, convex, film-coated tablet with 'RMB' marking on one side and breakline on the other.

Pharmaniaga Clarithromycin Tablet 500mg
Yellow, oblong, convex, film-coated tablet, plain on one side and Pharmaniaga icon on the other.

Pharmaniaga Clarithromycin Tablet 250mg

- *Ingredients:*

Active ingredient(s): - Clarithromycin 250mg
Inactive ingredient(s): - Croscarmellose Sodium, Microcrystalline Cellulose, Opadry Yellow, Sodium Lauryl Sulphate, Magnesium Stearate, Purified Water, Colloidal Silicon Dioxide

Pharmaniaga Clarithromycin Tablet 500mg

- *Ingredients:*

-Active ingredient(s): - Clarithromycin 500mg
-Inactive ingredient(s): - Croscarmellose Sodium, Microcrystalline Cellulose, Opadry Yellow, Sodium Lauryl Sulphate, Magnesium Stearate, Purified Water, Colloidal Silicon Dioxide

- *MAL number(s):*

Pharmaniaga Clarithromycin Tablet 250mg: MAL20021383AZ

Pharmaniaga Clarithromycin Tablet 500mg:
MAL20021384AZ

Manufacturer:
Pharmaniaga Manufacturing Berhad (198001006232),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder:
Pharmaniaga Manufacturing Berhad (198001006232),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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