

KLACID MR 500MG TABLET

Clarithromycin (500mg)

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What Klacid® MR is used for

Each KLACID® MR 500 MG TABLET contains 500 mg of the active ingredient Clarithromycin.

KLACID® MR 500 MG

TABLET are used to treat infections such as:

1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infections
3. Mild to moderate skin and tissue infections, e.g. cellulitis, folliculitis or erysipelas.

KLACID® MR 500 MG

TABLET are used in adults and children 12 years and older.

How Klacid® MR works

Klacid belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) which cause infections.

Before you use Klacid® MR

- *When you must not use it*

Do not take KLACID® MR 500 MG TABLET if you are taking any of the following medicines: domperidone (used for nausea & vomiting).

Do not take Klacid® MR 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 ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) 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. Consult your doctor for advice on alternative medicines.
- are taking other medicines which are known to cause serious disturbances in heart rhythm.
- are taking lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood).
- are taking oral midazolam (a sedative).
- have abnormally low levels of potassium in your blood (hypokalaemia).
- have severe liver disease with kidney disease.
- or someone in your family has a history

of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called "long QT syndrome".

- are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina)
- are taking colchicine (usually taken for gout)

- *Before you start to use it*

- if you have abnormally low levels of magnesium in your blood (hypomagnesaemia) consult your doctor before taking these tablets.

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- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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)
- atorvastatin, rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood). Statins can cause rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.
- nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (used to lower blood glucose levels)
- gliclazide or glimepiride (sulphonylureas used in the treatment of type II diabetes)
- theophylline (used in patients with breathing difficulties such as asthma)
- triazolam, alprazolam or intravenous or oromucosal midazolam (sedatives)

- cilostazol (for poor circulation)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- tacrolimus (immune suppressants)
- etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (anti-viral drugs used in the treatment of HIV)
- rifabutin, rifampicin, rifapentine, fluconazole, itraconazole (used in the treatment of certain bacterial infections)
- tolterodine (for overactive bladder)
- verapamil, amlodipine, diltiazem (for high blood pressure)
- sildenafil, vardenafil and tadalafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- St John's Wort (a herbal product used to treat depression)
- quetiapine or other antipsychotic medicines
- other macrolide medicines
- lincomycin and clindamycin (lincosamides - a type of antibiotic)

How to use Klacid® MR

- How much to use

The usual dose of KLACID® MR 500 MG TABLET in adults and children 12 years of age or older is 500 mg once-daily with food. In more severe

infections, the dosage may be increased to 1000 mg once-daily (2 x 500 mg). The usual duration of therapy is 5 to 14 days, excluding treatment of community acquired pneumonia and sinusitis which require 6 to 14 days therapy.

- When to use it

Klacid® MR tablets should be taken with food and must be swallowed whole and not chewed.

- How long to use it

Do not stop taking KLACID® MR 500 MG TABLET, even if you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

If you forget to take a dose of KLACID® MR 500 MG TABLET, take it as soon as you remember. Do not take more tablets in one day than your doctor has told you to.

- If you use too much (overdose)

If you accidentally take more KLACID® MR 500 MG TABLET in one day than your doctor has told you to, or if a child accidentally swallows some tablets, contact your doctor or nearest hospital emergency department immediately. An overdose of KLACID® MR 500 MG TABLET is likely to cause vomiting and stomach pains.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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While you are using

Klacid® MR

- *Things you must do*

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine as the safety of KLACID® MR 500 MG TABLET in pregnancy and breast-feeding is not known.

- *Things you must not do*

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*

KLACID® MR 500 MG

TABLET may make you feel dizzy or drowsy. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

Side effects

Like all medicines, KLACID® MR 500 MG TABLET can cause side effects although not everybody gets them. If you suffer from any of the following at any time during your treatment STOP TAKING your tablets and contact your doctor immediately:

- severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor.
- a rash, difficulty breathing, fainting or swelling of the face and throat. This is a sign that you may

have developed an allergic reaction.

- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These are signs that your liver may not be working properly.
- severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

Common side effects (may affect up to 1 in 10 people) include;

- difficulty sleeping
- changes in sense of taste
- headache
- widening of blood vessels
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- a change in the way the liver works
- skin rash
- increased sweating

Uncommon side effects (may affect up to 1 in 100 people) include:

- high temperature
- swelling, redness or itchiness of the skin.
- oral or vaginal 'thrush' (a fungal infection)

- inflammation of the stomach and intestines
- decrease of the levels of blood platelets (blood platelets help stop bleeding)
- decrease in white blood cells (leukopenia)
- decrease in neutrophils (neutropenia)
- stiffness
- chills
- increase of eosinophils (white blood cells involved in immunity)
- exaggerated immune response to a foreign agent
- lack or loss of appetite
- anxiety, nervousness
- drowsiness, tiredness, dizziness or shaking
- involuntary muscle movements
- vertigo
- ringing in the ears or hearing loss
- chest pain or changes in heart rhythm such as palpitations or an irregular heartbeat
- asthma: lung disease associated with tightening of air passages, making breathing difficult
- nose bleed
- blood clot that causes sudden blockage in a lung artery (pulmonary embolism)
- inflammation of the lining of the gullet (oesophagus) and lining of the stomach
- anal pain
- bloating, constipation, wind, burping
- dry mouth

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- situation where the bile (fluid made by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis)
- inflammation of the skin characterized by the presence of the bullae which are filled with fluid, itchy and painful rash
- muscle spasms, muscle pain or loss of muscle tissue. If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily), clarithromycin may worsen these symptoms.
- raised abnormal kidney and liver function blood test and raised blood tests
- feeling weak, tired and having no energy
- paraesthesia, more commonly known as ‘pins and needles’
- loss of taste or smell or inability to smell properly
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- loss of blood (haemorrhage)
- inflammation of the pancreas
- discolouration of the tongue or teeth
- acne
- change in the levels of products produced by the kidney, inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination)

Not known side effects (frequency cannot be estimated from the available data):

- Inflammation of the colon
- bacterial infection of the outer layers of the skin
- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- confusion, loss of bearings, hallucinations (seeing things), change in sense of reality or panicking, depression, abnormal dreams or nightmares and mania (feeling of elation or over-excitement)
- convulsion (fits)

KLACID® MR 500 MG TABLET may cause severe allergy and serious skin reactions. Stop using Klacid and seek medical assistance immediately if you experience any of the following symptoms: Skin reddening, blisters, rash, fever, sore throat or eye irritation.

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 Klacid® MR

- *Storage*

Keep this medicine out of sight and reach of children. Do not use these tablets after their use-by (exp) date which is printed on the blister pack. Do not store above 30°C. Store in the original package.

- *Disposal*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- *What it looks like*

KLACID® MR 500 MG TABLET are yellow, oval, modified release tablets.

- *Ingredients*

Active ingredient
Each tablet contains 500 mg of the active ingredient clarithromycin.

Inactive ingredient

The other ingredients are: citric acid, sodium alginate, sodium calcium alginate, lactose, povidone, talc, stearic acid, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide, sorbic acid, quinoline yellow (E104 aluminium lake)

- *MAL Number*

KLACID® MR 500 MG TABLET
MAL18086120ACZ

Manufacturer and Product Registration Holder

- *Manufacturer*

AbbVie S.r.l.
S.R. 148 Pontina KM 52, SNC-Campoverde di Aprilia (LT), 04011 Italy

- *Product Registration Holder & Importer*

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Abbott Laboratories (M) Sdn.
Bhd.
27-02, Level 27, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor
Darul Ehsan, Malaysia

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