

KLACID TABLET 500MG

Clarithromycin (500mg)

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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.

The full name of your medicine is KLACID® TABLET 500MG. In this leaflet the shorter name Klacid® is used.

What is in this leaflet

1. What Klacid® is used for
2. How Klacid® works
3. Before you use Klacid®
4. How to use Klacid®
5. While you are using Klacid®
6. Side effect
7. Storage and Disposal of Klacid®
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

1. What Klacid® is used for

Each Klacid® tablet contains 500 mg of the active ingredient *clarithromycin*.

Klacid® tablets are used to treat infections such as:

1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infections

3. Mild to moderate tissue infections, such as cellulitis, folliculitis and erysipelas
 4. *Helicobacter pylori* infection associated with duodenal ulcer
- Klacid 500mg Tablets is indicated in adults and children 12 years and older.

2. How Klacid® works

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

3. Before you use Klacid®

- Do not take Klacid if you are taking any of the following medicines: domperidone (used for nausea & vomiting).

Do not take Klacid® tablets if you;

- know that you are **allergic** to *clarithromycin*, side 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 (HMGCoA 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.

- 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:

KLACID TABLET 500MG

Clarithromycin (500mg)

- 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 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)
- 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)

4. How to use Klacid®

- How much to use

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

Always take Klacid® Tablets 500mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one 250mg tablet twice daily. In more severe infections, the dosage can be increased to 500mg twice daily. The usual duration of therapy is 5 to 14 days, excluding treatment of community acquired pneumonia and sinusitis which require 6 to 14 days of therapy.

- When to use it

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

- How long to use it

Do not stop taking Klacid® tablets, 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 Klacid 500mg Tablets, take one as soon as you remember. Do not take more tablets in one day than your doctor has told you to.

Do not stop taking Klacid 500mg Tablets, 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 use too much (overdose)

If you accidentally take more Klacid 500mg Tablets 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 500mg Tablets 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.

5. While you are using Klacid®

- Things you must do

If you are pregnant or breastfeeding, 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® tablets in pregnancy and breastfeeding is not known.

- Things you must not do

- rifabutin, rifampicin, rifapentine, fluconazole,

KLACID TABLET 500MG

Clarithromycin (500mg)

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® tablets 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.

6. Side effects

Like all medicines, Klacid® tablets 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 StevensJohnson 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
- 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

KLACID TABLET 500MG

Clarithromycin (500mg)

- feeling weak, tired and having no energy

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)
- 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)

Klacid 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.

Reporting of side effects

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)]

7. Storage and Disposal of Klacid®

- 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.

8. Product Description

- *What it looks like* Klacid® tablets are pale yellow, oval, immediate release tablets.

- Ingredients

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

Inactive ingredient

The other ingredients are: croscarmellose sodium, cellulose

microcrystalline, silicon dioxide, povidone, stearic acid, magnesium stearate, talc, hypromellose, sorbitan monooleate, propylene glycol, titanium dioxide, vanillin, quinoline yellow (E104 aluminium lake), hydroxypropylcellulose, sorbic acid.

-MAL Number

KLACID® TABLET 500MG

- MAL18106039ACZ

9. 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:

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

10. Date of Revision

30/03/2022

NPRA(R2/1)190809/216