



PATIENT INFORMATION LEAFLET ON KLACID® 250mg FILM-COATED TABLETS and KLACID® FORTE 500mg FILM-COATED TABLETS (Clarithromycin)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Klacid tablets and Klacid Forte tablets are and what they are used for

Each Klacid tablet contains 250mg of the active ingredient clarithromycin. Each Klacid Forte tablet contains 500mg of the active ingredient clarithromycin.

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

Klacid tablets and Klacid Forte tablets are used to treat infections such as:

1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and soft tissue infections such as cellulitis, folliculitis or erysipelas
4. Infections caused by certain types of bacteria called Mycobacteriae
5. *Helicobacter pylori* infection associated with duodenal ulcer

2. Before taking Klacid tablets or Klacid Forte tablets

Do not take Klacid tablets or Klacid Forte 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.
- you are taking medicines called ergot alkaloids, for example ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine. Consult your doctor for advice on alternative medicines.
- you are taking medicines called simvastatin or lovastatin (used to lower increased blood fats such as cholesterol and triglycerides).
- you are taking medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride or pimozone tablets as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- you are taking other medicines which are known to cause serious disturbances in heart rhythm
- you are taking medicines called ticagrelor or ranolazine (for angina or to reduce the chance of heart attack or stroke)
- you are taking a medicine called colchicine.
- you have abnormally low levels of potassium in your blood (hypokalaemia).
- you are taking oral midazolam (for epilepsy).
- you have any liver and/or kidney problems.
- you 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”.

Klacid tablets and Klacid Forte tablets are not suitable for use in children under 12 years of age.

Take special care with Klacid tablets and Klacid Forte tablets;

- if you have heart problems
- if you are pregnant or breast feeding
- if you need to have intravenous or oromucosal (absorbed in the mouth) midazolam
- if you have abnormally low levels of magnesium in your blood (hypomagnesaemia)

If any of these apply to you, consult your doctor before taking Klacid tablets or Klacid Forte tablets.

If you develop severe or prolonged diarrhoea during or after receiving Klacid tablets or Klacid Forte tablets, tell your doctor **immediately**, as this could be a symptom of more serious conditions such as pseudomembranous colitis or clostridium difficile associated diarrhoea.

If you develop any symptoms of liver dysfunction such as anorexia (loss of appetite), yellowing of the skin or whites of the eyes, dark urine, itching or tender abdomen, stop taking Klacid tablets or Klacid Forte tablets and tell your doctor **immediately**.

Long term use of Klacid tablets or Klacid Forte may lead to infection with resistant bacteria and fungi.

Each Klacid tablet contains 3.4 mg of sodium. Each Klacid Forte tablet contains 6.1 mg of sodium. To be taken into consideration by patients on a controlled sodium diet.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a prescription.

This is especially important if you are taking medicines called;

- digoxin, quinidine or disopyramide (used to treat heart problems). Your heart may need to be monitored (ECG test) or you may need to have blood tests if you take clarithromycin with some medicines used to treat heart problems
- warfarin, or any other anticoagulant (used to thin your blood). It may be necessary to have blood tests to check that your blood is clotting efficiently
- omeprazole (used for the treatment of indigestion and stomach ulcers) unless your doctor has prescribed it for you to treat *Helicobacter pylori* infection associated with duodenal ulcer
- ergot alkaloids such as ergotamine or dihydroergotamine (for the treatment of migraine)
- colchicine (for the treatment of gout). Your doctor may wish to monitor you
- theophylline (used in patients with breathing difficulties such as asthma)
- terfenadine or astemizole (for hay fever or allergy)
- triazolam, alprazolam or midazolam (sedatives)
- cilostazol (for poor circulation)
- cisapride or cimetidine (for stomach disorders)
- carbamazepine, valproate, phenytoin or phenobarbital (for the treatment of epilepsy)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- ciclosporin, tacrolimus or sirolimus (immune suppressants used for organ transplants and severe eczema)
- pimozone or St. John's wort (for mental health problems)
- rifabutin, rifampicin, rifapentine, fluconazole and itraconazole (treatments for infectious diseases)
- verapamil, amlodipine or diltiazem (for high blood pressure)
- tolterodine (for overactive bladder)
- simvastatin and lovastatin (known as HMG-CoA reductase inhibitors for the treatment of high cholesterol)
- ritonavir, efavirenz, nevirapine, atazanavir, saquinavir, etravirine and zidovudine (anti-viral or anti-HIV drugs)
- 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)
- insulin, repaglinide or nateglinide (medicines for the treatment of diabetes)
- quetiapine or other antipsychotic medicines

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or if you are breast-feeding, consult your doctor before taking Klacid tablets or Klacid Forte tablets as their safety in pregnancy and breast-feeding is not known.

Driving and operating machinery

Klacid tablets and Klacid Forte tablets may cause dizziness, vertigo, confusion and disorientation. If you are affected do not drive or use machines.

3. Taking Klacid tablets or Klacid Forte tablets

Always take Klacid tablets and Klacid Forte tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is;

For chest infections, throat or sinus infections and skin and soft tissue infections:

The usual dose of Klacid tablets or Klacid Forte tablets for adults and children over 12 years is 250mg twice daily for seven days, e.g. one Klacid 250mg tablet in the morning and one in the early evening. Your doctor may increase the dose to one Klacid Forte 500mg tablet twice daily in severe infections.

Klacid tablets and Klacid Forte tablets should be swallowed with at least half a glass of water.

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

For the treatment of infections caused by certain types of bacteria called Mycobacteria

For treatment or prevention of such infections, the usual dose in adults is 500mg twice daily.

For the treatment of *Helicobacter pylori* infection associated with duodenal ulcers:

There are a number of effective treatment combinations available to treat *Helicobacter pylori* in which Klacid tablets and Klacid Forte tablets are taken together with one or two other drugs.

These combinations include the following:

- a) One Klacid Forte 500mg tablet taken twice a day together with amoxycillin 1000mg taken twice a day with a proton pump inhibitor at the recommended daily dose for 7 days (7 day Triple Therapy).
- b) One Klacid Forte 500mg tablet taken twice a day together with a proton pump inhibitor at the recommended daily dose plus metronidazole 400mg taken twice a day for 7 days (7 day Triple Therapy).
- c) One Klacid Forte 500mg tablet taken twice a day together with amoxycillin, 1000mg taken twice a day plus omeprazole, 20mg taken once a day for 7-10 days (7-10 day Triple Therapy).

The treatment combination which you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you. If you are unsure which tablets you should be taking or how long you should be taking them for, please consult your doctor for advice.

If you take more Klacid tablets or Klacid Forte tablets than you should

If you accidentally take more 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 tablets or Klacid Forte tablets is likely to cause vomiting and stomach pains.

If you forget to take Klacid tablets or Klacid Forte tablets

If you forget to take a dose of your 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 your 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.

4. Possible side effects

Like all medicines, Klacid tablets and Klacid Forte tablets can cause side effects although not everybody gets them.

If you develop severe or prolonged diarrhoea, which may have blood or mucus in it, during or after taking Klacid tablets or Klacid Forte tablets, consult your doctor immediately, as these could be symptoms of more serious conditions such as pseudomembranous colitis or clostridium difficile associated diarrhoea. Diarrhoea may occur over two months after treatment with clarithromycin.

If you develop a rash, difficulty breathing, fainting or swelling of the face and throat, contact your doctor immediately as these may be signs of an allergic reaction and may need emergency treatment.

If you develop loss of appetite, yellowing of the skin (jaundice), dark urine, itching or tenderness in the abdomen, contact your doctor immediately as these may be signs of liver failure.

Other side effects of Klacid (all formulations) may include:

Very common (affects more than 1 user in 10):

- inflammation of a vein (phlebitis) at the site of injection (Klacid IV)

Common (affects 1 to 10 users in 100):

- difficulty sleeping (insomnia)
- changes in sense of taste
- headache
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- abnormal liver function blood tests
- rash, excessive sweating, flushing
- pain or inflammation at the site of injection (Klacid IV)

Uncommon (affects 1 to 10 users in 1000):

- infections of the skin or vagina, yeast infections (thrush)
- change in the level of white blood cells in the blood (which can make infections more likely)
- change in the levels of blood platelets in the blood (increased risk of bruising, bleeding or blood clots)
- allergic reaction
- anorexia, decreased appetite
- anxiety, nervousness
- fainting, dizziness, drowsiness, tremor, involuntary movements of the tongue, face, lips or limbs
- spinning sensation (vertigo), ringing in the ears, hearing loss
- fast, pounding heart (palpitations), changes in heart rhythm or heart stopping
- breathing problems (asthma), nosebleed
- blood clot in the lungs
- stomach problems such as bloating, constipation, wind (flatulence), belching, heartburn or anal pain,
- inflammation of the lining of the stomach or oesophagus (the tube connecting your mouth with your stomach)
- sore mouth, dry mouth, inflammation of the tongue
- liver problems such as hepatitis or cholestasis which may cause yellowing of the skin (jaundice), pale stools or dark urine
- increase in liver enzymes
- itching, hives, inflammation of the skin
- stiffness, aches or spasms in the muscles
- kidney problems such as raised levels of protein normally excreted by the kidneys or raised levels of kidney enzymes
- fever, chills, weakness, fatigue, chest pain or general feeling of discomfort
- abnormal blood test results

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

- infection of the colon
- infection of the skin
- swelling of the skin around the face and the throat. This may cause difficulty in breathing (angioedema)
- psychotic disorder, confusion, change in sense of reality, depression, loss of bearings (disorientation), hallucinations (seeing things), abnormal dreams (nightmares), manic episodes.
- convulsions
- changes or loss in sense of taste and/or smell
- paraesthesia (tingling and burning sensation in the skin, numbness, ‘pins and needles’ sensation)
- deafness
- bleeding
- inflammation of the pancreas
- discoloration of the tongue, tooth discolouration
- liver failure, jaundice (yellowing of the skin)
- rare allergic skin reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis (which cause severe illness with ulceration of the mouth, lips and skin), DRESS (which causes severe illness with rash, fever and inflammation of internal organs)
- acne
- muscle disease (myopathy), breakdown of muscle tissue (rhabdomyolysis)
- inflammation of the kidney (which can cause swollen ankles or high blood pressure) or kidney failure

Consult your doctor immediately if you develop any of these problems or have any other unexpected or unusual symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Klacid tablets or Klacid Forte tablets

Keep out of the sight and reach of children.

Do not use these tablets after their use-by (expiry) date which is printed on the box and indented on the blister strip. The expiry date refers to the last day of the month.

Do not store above 25°C. Store in the original package in order to protect from light.

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.

6. Contents of the pack and other information

What Klacid tablets and Klacid Forte tablets contain

Each Klacid tablet contains 250mg of the active ingredient clarithromycin. The other ingredients are; Quinolone Yellow Aluminium Lake (E104), croscarmellose sodium, starch pregelatinised, microcrystalline cellulose, silicon dioxide, povidone, stearic acid, magnesium stearate, talc, hypromellose, propylene glycol, sorbitan monooleate, hypromellose, titanium dioxide (E171), vanillin and sorbic acid.

Each Klacid Forte tablet contains 500mg of the active ingredient clarithromycin. The other ingredients are; Quinolone Yellow Aluminium Lake (E104), croscarmellose sodium, microcrystalline cellulose, silicon dioxide, povidone, stearic acid, magnesium stearate, talc, hypromellose, propylene glycol, sorbitan monooleate, hypromellose, titanium dioxide (E171), vanillin and sorbic acid.

What Klacid tablets and Klacid Forte tablets look like and contents of the pack

Klacid tablets and Klacid Forte tablets are yellow, oval and film-coated.

Klacid 250mg tablets are available as single calendar packs containing 14 tablets. Klacid Forte 500mg tablets are available as single packs containing 14 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13.

Manufacturer:

AbbVie S.r.l.
S.R. 148 Pontina km 52 snc
04011 Campoverde di Aprilia (LT)
Italy

This leaflet applies only to Klacid tablets and Klacid Forte tablets and was prepared in April 2017