

Package leaflet: Information for the user

KLACID® FORTE 500 mg FILM-COATED TABLETS

(clarithromycin)

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 further questions, ask your doctor, pharmacist or nurse.
- 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Klacid Forte tablets are and what they are used for
2. What you need to know before you take Klacid Forte tablets
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1. What Klacid Forte tablets are and what they are used for

Each Klacid Forte tablet contains 500 mg 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 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 Mycobacteria
5. *Helicobacter pylori* infection associated with duodenal ulcer

2. What you need to know before you take Klacid Forte

Do not take 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 astemizole or terfenadine (for hay fever or allergies), cisapride or domperidone (for stomach disorders) or pimozone (to treat certain psychiatric diseases), as taking these medicines with Klacid Forte tablets can 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 anxiety or to help sleep)
- 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 Forte tablets are not suitable for use in children under 12 years of age.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking 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 Forte tablets.

If you develop severe or prolonged diarrhoea during or after receiving 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 Forte tablets and tell your doctor **immediately**.

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

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

Other medicines and Klacid Forte tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Klacid Forte must not be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimozone, ticagrelor, ranolazine, colchicine, some medicines for treating high cholesterol and medicines that are known to cause serious disturbances in heart rhythm (see under **Do not take Klacid Forte tablets**).

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- 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
- theophylline (used in patients with breathing difficulties such as asthma)
- triazolam, alprazolam or midazolam (sedatives)
- cilostazol (for poor circulation)
- carbamazepine, valproate, phenytoin or phenobarbital (for the treatment of epilepsy)
- methylprednisolone (a corticosteroid)
- ibritinib or vinblastine (for treatment of cancer)
- ciclosporin, tacrolimus or sirolimus (immune suppressants used for organ transplants and severe eczema)
- 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)
- tadalafil (for overactive bladder)
- 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 Forte tablets as their safety in pregnancy and breast-feeding is not known.

Driving and using machinery

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Klacid Forte tablets

Always take 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 250 mg twice daily for 6 to 14 days, e.g. one Klacid 250 mg tablet in the morning and one in the early evening. Your doctor may increase the dose to one Klacid Forte 500 mg tablet twice daily in severe infections. 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 500 mg 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 Forte tablets are taken together with one or two other drugs.

These combinations include the following:

- a) One Klacid Forte 500 mg tablet taken twice a day together with amoxicillin 1000 mg 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 500 mg tablet taken twice a day together with a proton pump inhibitor at the recommended daily dose plus metronidazole 400 mg taken twice a day for 7 days (7 day Triple Therapy).
- c) One Klacid Forte 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus omeprazole, 20 mg 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 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 Forte tablets is likely to cause vomiting and stomach pains.

If you forget to take 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.

If you stop taking Klacid Forte tablets

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.

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

4. Possible side effects

Like all medicines, 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 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.

Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from available data).

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
- discolouration of the tongue, tooth discolouration
- liver failure, jaundice (yellowing of the skin)
- rare allergic skin reactions such as AGEF (which causes a red scaly rash with bumps under the skin and blisters) 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 HPRC 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 Forte tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and blister strip after EXP. The expiry date refers to the last day of that month. Do not store above 25 °C.

Store in the original package in order to protect from light.

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.

6. Contents of the pack and other information

What Klacid Forte tablets contain

The active substance is clarithromycin. Each Klacid Forte tablet contains 500 mg 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 oleate, hypromellose, titanium dioxide (E171), vanillin and sorbic acid. Products imported from Greece and Netherlands also contain pregelatinised starch.

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

Product imported from Czech Republic, Greece, Spain:

Yellow, ovaloid, film-coated tablets

Klacid is marketed in Greece under the name Klaricid.

Product imported from the Netherlands:

Yellow ovaloid film-coated tablets with the Abbott logo embossed on one side and plain on the other side.

Blister packs containing 14 or 21 tablets. Not all pack sizes may be marketed.

Manufacturer:

Abbott S.R.L, 04010 Campoverde di Aprilia, Italy or Abbott Laboratories Ltd., UK or AbbVie S.R.L, 04010 Campoverde di Aprilia, Italy or Aesica Queenborough Limited, Queenborough, Kent ME11 5EL, UK.

PARALLEL PRODUCT AUTHORISATION NUMBER:

Klacid Forte 500 mg Tablets PPA 465/51/2

Klacid is a registered trademark of BGP Products S.a.r.l.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

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