Package leaflet: Information for the patient

Klacid® IV 500mg

Powder for Concentrate for Solution for Infusion
(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 any further questions, ask your doctor, pharmacist or nurse.
• If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Klacid IV is and what it is used for

Klacid IV contains the active ingredient clarithromycin. Klacid IV belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) which cause infections.
Klacid IV is used whenever an intravenous (injection into the vein) antibiotic is required to treat severe infections or, alternatively, if a patient cannot swallow Klacid in the tablet formulation.
It is 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

2. What you need to know before you receive Klacid IV

Do not receive Klacid IV if;
• you know that you are **allergic** to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in Klacid IV.
• 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 pimozide (to treat certain mental health disorders) as taking these medicines with Klacid IV 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, ivabradine or ranolazine (for angina or to reduce the chance of heart attack or stroke)
• you are taking a medicine called colchicine.
• you are taking a medicine called lomitapide.
• you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)
• 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 an abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.

Klacid IV is not suitable for use in children under 12 years of age.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before receiving Klacid IV:
• 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 any of these apply to you, consult your doctor before being given Klacid IV.
If you develop severe or prolonged diarrhoea during or after receiving Klacid IV, tell your doctor **immediately**, as this could be a symptom of more serious conditions such as pseudomembranous colitis or clostridioides 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, tell your doctor **immediately.**
Long term use of Klacid IV may lead to infection with resistant bacteria and fungi.

Other medicines and Klacid IV

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.
Klacid IV must not be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimozide, 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 receive Klacid IV**).
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 e.g. dabigatran, rivaroxaban, apixaban, edoxaban (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)
• ibrutinib 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)
• tolterodine (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
 hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria).
Taking these medicines at the same time as clarithromycin may increase the chance of getting abnormal heart rhythms and other serious side effects that affect your heart
 corticosteroids, given by mouth, by injection or inhaled (used to help suppress the body's immune system - this is useful in treating a wide range of conditions)

Pregnancy and breast-feeding
If you are pregnant, trying to become pregnant, or are breast-feeding, consult your doctor before receiving Klacid IV as the safety of clarithromycin in pregnancy or breast-feeding is not known.

Driving and using machines
Klacid IV 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 vial, that is to say essentially 'sodium-free'.

3. How is Klacid IV given?
Klacid IV is prepared by your doctor or nurse by dissolving the powder in the vial in sterile water. The solution obtained is added to a larger volume of sterile liquid. Klacid IV is given to you slowly through a needle, into your vein over a period of at least an hour.
Adults, elderly and children over 12 years of age:
The usual dose of Klacid IV is 1.0g per day, split into two doses, for 2 to 5 days. Your doctor will work out the correct dose for you.
Children under 12 years:
Children under 12 years should not be given Klacid IV. Your doctor will prescribe another suitable medicine for your child.
If a child accidentally swallows some of this medicine, seek medical advice urgently.
Patients with renal impairment:
The dosage of Klacid IV should be reduced to half of the normal recommended.
If you are given more Klacid IV than you should have
As Klacid IV is given to you by a doctor, an overdose is unlikely but symptoms may include vomiting and stomach pains.

4. Possible side effects
Like all medicines, this medicine 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 being given Klacid IV, consult your doctor immediately, as these could be symptoms of more serious conditions such as pseudomembranous colitis or clostridioides 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

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

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 AGEP (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 the national reporting system (details below). By reporting side effects you can help provide more information on the safety of this medicine.
In Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
In Malta: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Klacid IV

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 carton and vial. The expiry date refers to the last day of that month.
Do not store above 30°C. Store in the original container to protect from light. The reconstituted and diluted solutions can be stored for 24 hours at 2° - 8°C.
For single use only, discard any unused contents.
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 to protect the environment.

6. Contents of the pack and other information

What Klacid IV contains
The active substance is Clarithromycin.
The other ingredients are: Lactobionic acid and sodium hydroxide (for pH-adjustment).
What Klacid IV looks like and contents of the pack
Klacid IV is a white to off-white caked, lyophilised powder and is available in glass tubing 15ml or 30ml vials containing 500mg of clarithromycin (as lactobionate) as the active ingredient. When made up with Water for Injections, each millilitre (ml) of solution contains approximately 1.9mg of clarithromycin.
Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Viatris Healthcare Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland.
Manufacturer: Delpharm Saint Remy, Rue de l'Isle, 28380 Saint-Rémy-sur-Avre, France.
This leaflet applies only to Klacid IV 500mg Powder for Concentrate for Solution for Infusion.
This leaflet was last revised in March 2024

INFORMATION FOR THE HEALTHCARE PROFESSIONAL
KLACID IV 500mg POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
500 mg clarithromycin
Refer to the Summary of Product Characteristics for the full prescribing information
Method of administration
Klacid IV should be administered as an IV infusion over 60 minutes using a solution concentration of about 1.9mg/ml.
Clarithromycin should not be given as a bolus or an intramuscular injection.
Dilution:
Both dilution steps should be complete before use.
Prepare all solutions using aseptic techniques.
The final solution for infusion is prepared as follows:
1. Prepare the initial solution of clarithromycin I.V. by adding 10 ml of Sterile Water for Injection to the 500 mg vial. Use only Sterile Water for Injection, as other diluents may cause precipitation during reconstitution. Do not use diluents containing preservatives or inorganic salts. Note: When the product is reconstituted as directed above, the resulting solution contains an effective antimicrobial preservative; each ml contains 50 mg clarithromycin. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.
2. The reconstituted product (500 mg in 10 ml Water for Injection) should be added to a minimum of 250 ml of one of the following diluents before administration:

- 5% dextrose in Lactated Ringer's Solution,
- 5% dextrose,
- Lactated Ringer's,
- 5% dextrose in 0.3% sodium chloride,
- Normosol-M in 5% dextrose,
- Normosol-R in 5% dextrose,
- 5% dextrose in 0.45% sodium chloride,
- 0.9% sodium chloride.

Compatibility with other IV additives has not been established.
IMPORTANT: BOTH DILUENT STEPS SHOULD BE COMPLETED BEFORE USE.
Once reconstituted, the white to off-white caked, lyophilised powder forms a clear solution.
The concentration of the final reconstituted solution is approximately 1.9mg/ml. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.
For single use only. Discard any unused contents.

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