FPO

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INFORMATION FOR THE HEALTHCARE PROFESSIONAL
KLARICID® I.V. 500 mg
Powder for Concentrate for Solution for Infusion
Clarithromycin

Refer to the Summary of Product Characteristics for the full prescribing information.

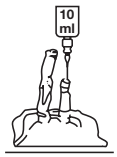
Method of administration
Refer to the summary of product characteristics for posology information.

Clarithromycin should not be given as a bolus or an intramuscular injection. Klaricid IV should be administered into one of the larger proximal veins as an IV infusion over 60 minutes, using a solution concentration of about 2mg/ml.

STEP 1

Add 10 ml sterilised Water for Injections into the vial and shake
Use within 24 hours
May be stored from 5°C up to room temperature

STEP 2



Add 10 ml from Step 1 to 250ml of a suitable diluent (see below)
This provides a 2mg/ml solution
Use within 6 hour (at room temperature) or within 24 hours if stored at 5°C

DO NOT USE
- Diluents containing preservatives
- Diluents containing inorganic salts

DO NOT USE
- Solution strengths greater than 2mg/ml (0.2%)
- Rapid infusion rates (<60 minutes)
- Failure to observe these precautions may result in pain along the vein

Recommended Diluents
5% dextrose in Lactated Ringer's Solution, 5% dextrose, Lactated Ringer's solution, 5% dextrose in 0.3% sodium chloride, Normosol-M in 5% dextrose, Normosol-R in 5% dextrose, 5% dextrose in 0.45% sodium chloride, or 0.9% sodium chloride. Compatibility with other IV additives has not been established.

Storage
Do not store above 30°C. Store in the original container as the powder is sensitive to light. See carton and vial for expiry date. The product should not be used after this date.

Product Licence Number: 46302/0018

Legal Category: POM

Marketing Authorisation Holder:
Mylan Products Ltd, 20 Station Close, Potters Bar, Herts, EN6 1TL, UK

Revised: July 2017

Mylan

PATIENT INFORMATION LEAFLET ON
KLARICID® IV 500 mg
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 further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. 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 or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4.

What is in this leaflet:

1. What Klaricid IV is and what it is used for
Klaricid IV contains the active ingredient clarithromycin. Klaricid belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) that cause infections.
Klaricid IV is used whenever an intravenous (injection into the vein) antibiotic is required to treat severe infections or, alternatively, if a patient cannot swallow Klaricid tablets.
It is used to treat infections such as:
1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and tissue infections

Klaricid IV is indicated in adults and children 12 years and older.

2. What you need to know before receiving Klaricid IV


Do not receive Klaricid 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 Klaricid IV.
- 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 disorders) 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)

Warnings and precautions
Talk to your doctor or pharmacist before being given Klaricid IV;
- if you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or abnormally low levels of magnesium in the blood (hypomagnesaemia))
- if you have any liver or kidney problems
- if you have, or are prone to, fungal infections (e.g. thrush)
- if you are pregnant or breast feeding

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

Other medicines and Klaricid IV

You should **not** be given Klaricid IV if you are taking any of the medicines listed in the section above "Do not receive Klaricid IV if you;"

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, or any other anticoagulant (for blood thinning)
- 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)
- ciclosporin, sirolimus and 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)

Please tell your doctor if you are taking oral contraceptive pills and diarrhoea or vomiting occurs, as you may need to take extra contraceptive precautions such as using a condom.

Pregnancy and breast-feeding
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 receiving the medicine as the safety of clarithromycin in pregnancy or breast-feeding is not known.

Driving and Using Machines:
Klaricid IV 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.

3. How is Klaricid IV given?
Klaricid 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. Klaricid IV is given to you slowly through a needle, into your vein over a period of at least an hour.
The recommended dose of Klaricid IV for adults and children over 12 years 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 should not be given Klaricid IV. Your doctor will prescribe another suitable medicine for your child.

If a child accidentally swallows some of this medicine, seek medical advice urgently.

If you are given more Klaricid IV than you should have
As Klaricid 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, Klaricid IV can cause side effects although not everybody gets them.

If you suffer from any of the following at any time during your treatment tell your doctor immediately as your treatment may need to be stopped:
- 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, tongue, lips, eyes 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 have inflammation and not be working properly.
- severe skin reactions such as painful blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis)
- a red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).
- rare allergic skin reactions which cause severe illness with ulceration of the mouth, lips and skin which causes severe illness with rash, fever and inflammation of internal organs (DRESS).
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

Other side effects

Common side effects (may affect up to 1 in 10 people) include;
- inflammation, tenderness or pain at the site of the injection
- difficulty sleeping
- changes in sense of taste
- headache
- widening of blood vessels
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- increased sweating

Uncommon side effects (may include 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
- 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)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Klaricid IV

Keep out of the sight and reach of children
Do not use after the expiry date on the carton and vial.
Do not store above 30°C. Store in the original container. The reconstituted solution will be stored for either 6 hours at room temperature or for 24 hours at 5° C.

6. Contents of the pack and other information

What Klaricid IV contains
Klaricid IV contains the active ingredient clarithromycin.
The other ingredients are; lactobionic acid and sodium hydroxide.
This medicinal product contains less than 23mg sodium (1mmol) per 500mg i.e. essentially "sodium-free".

What Klaricid IV looks like and contents of the pack
Klaricid IV is a white to off-white caked, lyophilized powder available in vials containing 739.5 mg clarithromycin lactobionate, corresponding to 500mg of clarithromycin as the active ingredient. When made up with Water for Injections, each millilitre (ml) of solution contains 2mg of clarithromycin.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder – Mylan Products Ltd, 20 Station Close, Potters Bar, Herts, EN6 1TL, UK
Manufacturer - FAMAR L'Aigle Usine St Remy, Rue de L'Isle, 28380 Saint Remy sur Avre, France.
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