

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Clarithromycin 500 mg Powder for Solution for Infusion**  
Clarithromycin

**Read all of this leaflet carefully before you start using 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 Clarithromycin Infusion is and what it is used for
2. What you need to know before you are given Clarithromycin Infusion
3. How Clarithromycin Infusion is given
4. Possible side effects
5. How to store Clarithromycin Infusion
6. Contents of the pack and other information

The name of your medicine is “Clarithromycin 500 mg Powder for Solution for Infusion” (referred to as Clarithromycin Infusion throughout this leaflet).

**1. What Clarithromycin Infusion is and what it is used for**

Clarithromycin Infusion contains the active substance clarithromycin, which is one of a group of medicines called “macrolide antibiotics”. These are used to kill the bacteria or ‘germs’ that cause infections.

Clarithromycin Infusion is used whenever an intravenous (injection into the vein) antibiotic is required to treat severe infections or, alternatively, if a patient cannot swallow Clarithromycin tablets.

Your doctor has decided to give you Clarithromycin Infusion to treat infections such as:

- Chest infections such as bronchitis and pneumonia
- Throat and sinus infections
- Skin and soft tissue infections.

Clarithromycin Infusion is used to treat adults and children aged 12 years and older.

**2. What you need to know before you are given Clarithromycin Infusion**

**You should not be given Clarithromycin Infusion if you:**

- are allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients of this medicine (listed in section 6)
- 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 or domperidone (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 or magnesium in your blood (hypokalemia or hypomagnesaemia)
- have severe liver disease as well as 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)
- are taking a medicine containing lomitapide.

If you are unsure, talk to your doctor or nurse.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before treatment with Clarithromycin Infusion

- if you are pregnant or breastfeeding
- if you have severe kidney problems
- if you have liver problems
- if you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or a history of heart rhythm problems)
- if you have or are prone to fungal infections (e.g. thrush).

### **Children**

Clarithromycin Infusion is not suitable for use in children under 12 years of age.

### **Other medicines and Clarithromycin Infusion**

You should not be given Clarithromycin Infusion if you are taking any of the following medicines:

- ergotamine or dihydroergotamine (for migraine headaches)
- cisapride or domperidone (for stomach problems)
- terfenadine or astemizole (for hay fever or allergies)
- pimozide (for schizophrenia)
- simvastatin or lovastatin (used to reduce cholesterol)
- ticagrelor or ranolazine (for heart problems and angina)
- other medicines which are known to cause serious disturbances in heart rhythm
- colchicine (usually taken for gout)
- oral midazolam (a sedative).

Tell your doctor or nurse if you are taking, have recently taken or might take any of the following medicines as your dose may need to be changed or you may need to have regular tests performed:

- rifampicin, rifapentine, rifabutin (used to treat some infections)
- fluconazole or itraconazole (anti-fungals)
- cilostazol (for poor circulation)
- digoxin, disopyramide or quinidine (for heart problems)
- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (used to thin your blood)
- carbamazepine, phenobarbital, valproate or phenytoin (for epilepsy)
- theophylline (used in patients with breathing difficulties such as asthma)
- alprazolam, triazolam or intravenous or oromucosal midazolam (sedatives)
- ciclosporin, sirolimus and tacrolimus (immune suppressants)
- zidovudine, ritonavir, efavirenz, nevirapine, atazanavir, saquinavir, etravirine (anti-viral drugs used in the treatment of HIV)
- quetiapine and other antipsychotic medicines
- methylprednisolone (a corticosteroid)
- omeprazole (for stomach ulcers and indigestion)
- sildenafil, tadalafil and vardenafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- vinblastine (for treatment of cancer)
- 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

- tolterodine (for overactive bladder)
- verapamil, amlodipine, diltiazem (for high blood pressure and angina)
- insulin, nateglinide, pioglitazone, repaglinide and rosiglitazone (used to lower blood glucose levels)
- gliclazide or glimepiride (sulphonylureas used in the treatment of Type II diabetes)
- St. Johns Wort (a herbal product used to treat depression)
- lincomycin and clindamycin (a type of antibiotic)
- other macrolide antibiotics
- ibrutinib (a cancer treatment)
- oral contraceptive pills (if diarrhoea or vomiting occurs, you may need to take extra contraceptive precautions such as using a condom)
- methadone (used in the treatment of opioid addiction).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you must tell your doctor or nurse before you are given this medicine, as the safety of clarithromycin in pregnancy or breast-feeding is not known.

### **Driving and using machines**

After taking this medicine, you may suffer dizziness, vertigo, confusion and disorientation. If these side effects occur, you should not drive or use machines.

## **3. How Clarithromycin Infusion is given**

Clarithromycin Infusion will usually be given by a doctor or nurse by an intravenous infusion ('drip').

The infusion is prepared by dissolving the powder in sterile water. The solution obtained is added to a larger volume of sterile liquid, and this is then infused (like being given a blood transfusion) into one of your veins for at least an hour.

### **Adults and children over 12 years**

The usual dose is 1 gram per day given in two doses, for 2-5 days.

Patients with kidney problems may be given a smaller dose.

Your doctor will work out the correct dose for you.

**Children under 12 years** should not be given Clarithromycin Infusion.

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

### **If you are given more Clarithromycin Infusion than you should have**

As this medicine 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, Clarithromycin Infusion 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 be inflamed 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**

#### **Very common side effects** (may affect more than 1 in 10 people)

- Injection site phlebitis

#### **Common side effects** (may affect up to 1 in 10 people)

- inflammation and tenderness or pain at the site of injection
- increased sweating
- nausea (feeling sick), vomiting (being sick), tummy pain and diarrhoea
- headache
- changes in sense of taste
- changes in liver function tests
- widening of blood vessels (causing redness)
- difficulty sleeping.

#### **Uncommon side effects** (may affect up to 1 in 100 people)

- oral or vaginal "thrush" (a fungal infection)
- swelling, redness or itchiness of the skin
- inflammation of the stomach and intestines
- decrease in white blood cells (leukopenia)
- decrease in neutrophils (neutropenia)
- decrease in the level of blood platelets (blood platelets help stop bleeding)
- increase in eosinophils (white blood cells involved in immunity)
- exaggerated immune response to a foreign agent
- stiffness
- chills
- anorexia, decreased appetite
- anxiety, nervousness
- loss of consciousness
- involuntary muscle movements
- drowsiness, tiredness, dizziness or shaking
- vertigo
- "ringing" in the ears or hearing loss
- heart attack
- 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
- dry mouth
- bloating, constipation, wind, burping

- 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
- fever
- chest pain or changes in heart rhythm such as palpitations or an irregular heartbeat
- raised abnormal kidney and liver function blood test and raised blood tests.

**Not known side effects** (frequency cannot be estimated from the available data)

- bacterial infection of the outer layers of the skin
- inflammation of the colon
- 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 overexcitement)
- loss of taste or smell or inability to smell properly
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- loss of blood (haemorrhage)
- convulsions (fits)
- inflammation of the pancreas
- tooth or tongue discolouration
- 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)
- paraesthesia, more commonly known as pins and needles.

**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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Clarithromycin Infusion**

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

Do not use Clarithromycin Infusion after the expiry date which is printed on the label and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Your doctor, pharmacist or nurse will know how to store Clarithromycin Infusion properly.

**6. Contents of the pack and other information**

**What Clarithromycin Infusion contains:**

- The active substance is Clarithromycin 500 mg
- The other ingredient is Lactobionic acid.

**What Clarithromycin Infusion looks like and contents of the pack**

Clarithromycin Infusion is a vial containing a white to off-white powder.  
Each vial contains 500 mg clarithromycin. Each carton contains 1 or 5 vials.

**Marketing Authorisation Holder**

Ibigen S.r.l.  
Via Fossignano, 2  
04011 Aprilia (LT)  
Italy

**Manufacturer**

Laboratorios Alcalá Farma S.L.,  
Madrid,  
Spain

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**INFORMATION FOR THE HEALTHCARE PROFESSIONAL**

**The following information is intended for medical or healthcare professionals only**

**Instructions for use and handling****Reconstitution (Step 1)**

Reconstitute each vial with 10 ml sterile water for injections (final volume: 10.75ml).  
Shake until the vial contents have dissolved. Use only sterile Water for Injection, as other diluents may cause precipitation during reconstitution. Do not use diluents containing preservatives or inorganic salts. Each ml contains 50 mg clarithromycin.

**Dilution (Step 2)**

The reconstituted solution should be added to a minimum of 250 ml of one of the following diluents before administration:

- 0.9% sodium chloride solution
- 5% dextrose solution
- 5% dextrose in 0.3% or 0.45% sodium chloride solution
- 5% dextrose in Ringer's solution
- 5% dextrose in Ringer's Lactate solution.

Each 1ml of the infusion solution prepared in this way contains 2 mg clarithromycin.

**IMPORTANT: BOTH DILUENT STEPS (1 and 2) SHOULD BE COMPLETED BEFORE USE.**

Clarithromycin 500 mg Powder for Solution for Infusion should be administered into one of the larger proximal veins as an IV infusion over 60 minutes, using a solution concentration of about 2 mg/ml. Clarithromycin should not be given as a bolus or an intramuscular injection.

For single use only. The vial and any unused solution should be disposed of in accordance with local requirements.

**Storage precautions:** Store below 25°C.

**Shelf life:**

Unopened vial: 48 months

*Reconstituted solution:* Chemical and physical in-use stability has been demonstrated for 24 hours at 5 - 25°C when reconstituted in 10 ml water for injections, and for 6 hours (at 25°C) or 24 hours (at 5°C) once diluted in 250 ml of appropriate diluent.

From a microbiological point of view, the product should be used immediately. 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.