

Package leaflet: Information for the patient

Clarithromycin 250 mg/5 ml granules for oral suspension

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 or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Clarithromycin is and what it is used for
2. What you need to know before you take Clarithromycin
3. How to take Clarithromycin
4. Possible side effects
5. How to store Clarithromycin
6. Contents of the pack and other information

1. What Clarithromycin is and what it is used for

Clarithromycin contains the active substance clarithromycin.

Clarithromycin belongs to a group of medicines called macrolide antibiotics. It stops the growth of certain bacteria.

Clarithromycin is used to treat:

- Chest infections, such as bronchitis and pneumonia
- Throat and sinus infections
- Skin and soft tissue infections
- Ear infections particularly inflammation of middle ear (acute otitis media).

Clarithromycin is used in children 6 months to 12 years old.

2. What you need to know before you take Clarithromycin

Do not give Clarithromycin to your child,

- if your child is allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients of this medicine (listed in section 6).
- if your child is taking medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or using ergotamine inhalers for migraine.
- if your child is taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride or domperidone (for stomach disorders) or pimozone (for mental health problems) as combining these medicines can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- if your child is taking other medicines which are known to cause serious disturbances in heart rhythm.
- if your child is 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).

- if your child is taking oral midazolam (sedatives).
- if your child has abnormally low levels of potassium or magnesium in their blood (hypokalaemia or hypomagnesaemia).
- if your child has **severe** liver disease with kidney disease.
- if your child or someone in their 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”.
- if your child is taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina).
- if your child is taking colchicine (usually taken for gout)
- if your child is taking a medicine containing lomitapide.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clarithromycin:

- if your child has heart problems (e.g. heart disease, heart failure, an unusually slow heart rate).
- if your child has any liver or kidney problems
- if your child has, or is prone to, fungal infections (e.g. thrush)

Other medicines and Clarithromycin

Your child should not take Clarithromycin if they are taking any of the medicines listed in the section above “Do not give Clarithromycin to your child”.

Tell your doctor or pharmacist if your child is taking, have recently taken or might take any of the following medicines as their dose may need to be changed or they may need to have regular tests performed:

- digoxin, quinidine or disopyramide (for heart problems)
- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (used to thin your blood)
- 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)
- ibrutinib or vinblastine (for treatment of cancer)
- ciclosporin, sirolimus and tacrolimus (immune suppressants)
- etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (anti-viral medicines used in the treatment of HIV)
- rifabutin, rifampicin, rifapentine, fluconazole, itraconazole (used in the treatment of certain bacterial or fungal 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)
- hydroxychloroquine or chloroquine (for autoimmune diseases)

Please tell your doctor if your daughter (of childbearing age) is taking oral contraceptive pills and diarrhoea or vomiting occurs, as they may need to take extra contraceptive precautions such as using a condom.

Pregnancy and breast-feeding

The safety of clarithromycin in pregnancy and breast-feeding is not known. As clarithromycin may be given to girls of childbearing age you should talk to your doctor before giving this medicine if pregnancy is known or suspected.

Driving and using machines

There are no data available on the effect of clarithromycin on the ability to drive or use machines. The potential for dizziness, vertigo, confusion and disorientation, which may occur with the medication, should be taken into account before patients drive or use machines.

Clarithromycin contains sucrose

5 ml suspension contains 2889 mg sucrose. This should be taken into account in patients with diabetes mellitus.

If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving this medicinal product.

Clarithromycin contains aspartame

This medicine contains 1 mg aspartame in each 5 ml suspension which is equivalent to 0.2 mg/ml. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Clarithromycin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml suspension, that is to say essentially “sodium-free”.

Clarithromycin contains sodium benzoate

This medicine contains 10 mg sodium benzoate in each 5ml suspension which is equivalent to 2 mg/ml.

3. How to take Clarithromycin

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses of Clarithromycin are given below:

Dosage

The dosage is based on body weight.

Weight (kg)	Age (years)	Dosage in ml (twice daily)
8 - 11	1 - 2	1.25
12 - 19	3 - 6	2.5

20 – 29	7 - 9	3.75
30 – 40	10 - 12	5.0

Children who weigh less than 8 kg should be given a dose of 0.15 ml/kg twice a day. Doctors may sometimes prescribe higher or lower doses than these.

Clarithromycin should be given twice a day, once in the morning and again in the early evening. It can be given at mealtimes if this is more convenient.

Method of administration

For oral use after reconstitution. Instructions for reconstitution, see below.

Shake the suspension well before each use and replace the cap firmly after use.

Duration of treatment

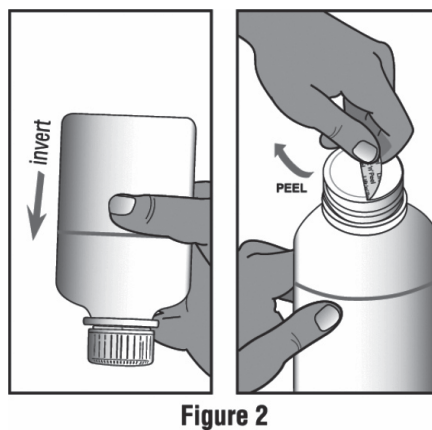
Clarithromycin is usually given for 5 to 10 days.

Instructions for Reconstitution

Step-A Remove bottle from the box.



Step-B Invert the bottle and shake it to loosen the powder until no powder is adhered to the bottom. Check them by holding the bottle upside down against light. Open the cap as instructed below, open the seal by lifting the tab and then peel off (See Figure 2).



Step-C Slowly add water up to ring mark. If necessary, hold the bottle against light in order to be able to recognize the correct filling level better. Close the bottle. Invert and shake well for about 1 minute until no powder is adhered to the bottom (See Figure 3). Check them by holding the bottle

upside down against light. Leave the suspension to settle and if it is necessary to add more water as to make it up to the ring mark, follow step D.

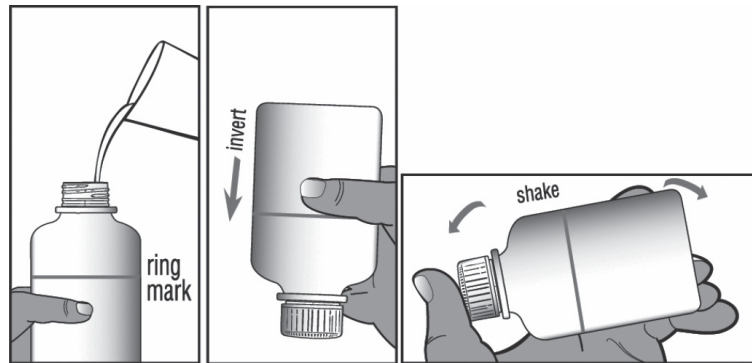


Figure 3

Step-D If necessary, add water again to make up level up to ring mark. If necessary, hold the bottle against light in order to be able to recognize the correct filling level better. Close the bottle. Invert and shake well until no powder is adhered to the bottom (See Figure 4). Check them by holding the bottle upside down against light.

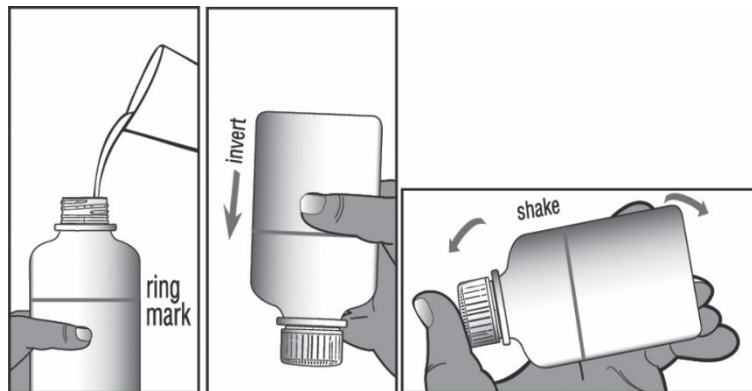


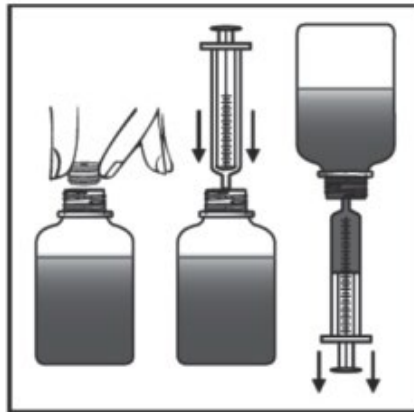
Figure 4

Instructions on Use

Clarithromycin is supplied with an oral syringe with an adaptor for the bottle to help you measure the right amount of medicine to give to your child. Please follow instructions given below carefully.

1. To open the bottle remove the child-proof cap from the bottle by pushing down on the cap while turning it anticlockwise.
2. Take the plastic circular adaptor from the carton and push this into the neck of the bottle. This should fit tightly and once it is in place it should not be removed.
3. Take the oral syringe out of the carton and ensure that the plunger is pressed down inside the barrel as far as it will go. This gets rid of any air that may be inside the barrel.
4. Insert the nozzle of the oral syringe into the hole in the adaptor.
5. Turn the bottle upside down. Keep hold of the bottle in one hand and the oral syringe in the other.
6. Hold the barrel of the oral syringe steady and slowly, pull the plunger down until you see the medicine fill the barrel to the mark which matches the number of ml that you need to give to your child.
7. Turn the bottle the correct way up. Keeping hold of the barrel, remove the whole oral syringe from the adaptor.

8. Put the oral syringe tip into your child's mouth. Drip the medicine in by pushing down the plunger gently while still holding the barrel. Don't hurry your child, allow time for him or her to swallow the medicine slowly. Alternatively, empty the measured dose from the oral syringe onto a spoon for your child to take the medicine from.
9. Replace the cap on the bottle of medicine.
10. Wash the oral syringe in warm soapy water and rinse well. Hold the oral syringe under water and move the plunger up and down several times to make sure the inside of the barrel is clean. Store the oral syringe in a hygienic place with the medicine.



Administration of the suspension dose

Clarithromycin can cause a bitter after-taste. This can be avoided by eating some food or drinking juice or water soon after intake of the suspension.



Administration of water or juice after medicine

Alternatively, the following amounts of water for the respective pack sizes can be added to the bottle once:

Pack	Volume of water to be added
50 ml Bottle	27 ml
60 ml Bottle	33 ml
70 ml Bottle	38 ml
100 ml Bottle	54 ml
140 ml Bottle	76 ml

Close the bottle and shake vigorously.

If you take more Clarithromycin than you should

If you accidentally give your child more Clarithromycin in one day than your doctor has told you to, or if your child accidentally swallows some extra medicine, contact your doctor or nearest hospital emergency department immediately. An overdose of Clarithromycin is likely to cause vomiting and stomach pains.

If you forget to take Clarithromycin

If you forget to give your child a dose of medicine, give one as soon as you remember. Do not give more Clarithromycin in one day than your doctor tells you to.

If you stop taking Clarithromycin

Do not stop giving this medicine even if your child feels better. It is important to give the medicine 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 or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If your child suffers from any of the following at any time during their treatment STOP giving the medicine and contact your doctor immediately:

- severe or prolonged diarrhoea, which may have blood or mucous 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 your child 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 child's liver have inflammation and may 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 (may affect up to 1 in 10 people):

- 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 (may affect up to 1 in 100 people):

- 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 your child suffers from myasthenia gravis (a condition in which the muscles become weak and tire easily), clarithromycin may worsen these symptoms
- raise of abnormal kidney and liver function blood test and raised blood tests
- feeling weak, tired and having no energy

Not known (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
- deafness
- 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 your child gets 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 Clarithromycin

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 bottle or carton. The expiry date refers to the last day of that month.

Store below 30°C. Do not refrigerate or freeze the reconstituted suspension.

Discard the unused portion after 14 days.

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 Clarithromycin contains

The active substance is clarithromycin.

Each 5 ml of the reconstituted suspension contains 250 mg clarithromycin.

The other ingredients are methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent, macrogol 1500, talc, carbomer, silica colloidal anhydrous, sucrose, aspartame (E951), xanthan gum (E415), monosodium citrate, sodium benzoate (E211), titanium dioxide (E171), peppermint flavour (containing modified food starch) and flavour tutti frutti (containing waxy maize maltodextrin, nature-identical flavouring substances, propylene glycol (E1520), modified waxy maize starch (E1450), and artificial flavouring substances).

What Clarithromycin looks like and contents of the pack

Granules for oral suspension

Clarithromycin is a white to off-white granular powder.

The following pack sizes are available:

V008

1 bottle with 34.72 - 38.37 g granules for preparation of 50 ml oral suspension or
1 bottle with 41.66 - 46.04 g granules for preparation of 60 ml oral suspension or
1 bottle with 48.61 - 53.72 g granules for preparation of 70 ml oral suspension or
1 bottle with 69.44 - 76.75 g granules for preparation of 100 ml oral suspension or
1 bottle with 97.21 - 107.44 g granules for preparation of 140 ml oral suspension.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Polarisavenue 87
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The Netherlands

Manufacturer:

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This medicinal product is authorised in the Member States of the EEA under the following names:

Germany	CLARITHROMYCIN BASICS 250 mg/5 ml Granulat zur Herstellung einer Suspension zum Einnehmen
Italy	Claritromicina SUN
Poland	Klabax EC
Romania	Klabax 250mg/5ml granule pentru suspensie orală
United Kingdom	Clarithromycin 250 mg/5ml granules for oral suspension

This leaflet was last revised in July 2022.