

## Package leaflet: Information for the user

### Clarithromycin 125 mg/5 ml Oral Suspension Clarithromycin 250 mg/5 ml Oral Suspension

**Read all of this leaflet carefully before you start giving this medicine to your child because it contains important information for your child.**

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

#### 1. What Clarithromycin Oral Suspension is and what it is used for

Clarithromycin is part of a group of antibiotics called macrolides. Clarithromycin works by destroying some types of bacteria that cause certain infections. Clarithromycin may be used to treat infections that are caused by bacteria in the chest, throat, sinuses and ear [particularly inflammation of middle ear (otitis media)] and infections of the skin and the layers of flesh just under the skin.

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

#### 2. What you need to know before you give Clarithromycin Oral Suspension

##### Do not give Clarithromycin Oral Suspension, 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).
- has abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)
- has severe liver disorders combined with kidney disorders
- 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"
- is taking:
  - medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers for migraine
  - medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride or pimozone tablets as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
  - other medicines which are known to cause serious disturbances in heart rhythm
  - oral midazolam (a sedative)
  - ticagrelor or ranolazine (for heart attack, chest pain or angina)
  - colchicine (usually taken for gout)

- lovastatin, simvastatin or atorvastatin (treatments to lower cholesterol)
- a medicine containing lomitapide

If any of the above applies to your child, consult your doctor for advice on alternative medicines.

### **Take special care with Clarithromycin Oral Suspension**

- If your child has abnormally low levels of magnesium in their blood (hypomagnesaemia) consult your doctor before giving Clarithromycin Oral Suspension.

### **Warnings and precautions**

Talk to your doctor or pharmacist before giving Clarithromycin Oral Suspension, if your child:

- has a liver or kidney disorder
- is resistant to other antibiotics such as clindamycin, lincomycin
- has heart problems (e.g. heart disease, heart failure, an unusually slow heart rate)
- is taking anticoagulants, e.g. warfarin (medicines to thin blood). Your child's prothrombin time should be monitored frequently.
- is taking medicines which can impair hearing e.g. aminoglycosides. Your doctor should check your child's ability to hear, if necessary.
- is taking medicines to lower blood sugar. Their effect might be increased by clarithromycin.
- has pneumonia, as the causing bacteria (*Streptococcus pneumoniae*) might be resistant against clarithromycin.
- has pharyngitis and there is no hypersensitivity or another contraindication to take penicillins.
- has, or is prone to, fungal infections (e.g. thrush)

If the bacteria are resistant against erythromycin A they might be resistant against clarithromycin, too.

If any of the above applies to your child, speak to your doctor.

Stop giving Clarithromycin Oral Suspension and tell your doctor, if your child:

- develops severe diarrhoea during or after treatment with Clarithromycin Oral Suspension. Medicines that prevent peristalsis (bowel movement) such as antidiarrhoeal treatments should be avoided.
- develops yellowing of skin (jaundice), skin irritation, dark urine, tender abdomen, or loss of appetite. These are signs that your child's liver may not be working properly.
- develops another infection.

### **Other medicines and Clarithromycin Oral Suspension**

Tell your doctor or pharmacist if your child is given, has recently been given or might be given any other medicines.

Do not give Clarithromycin Oral Suspension to your child and talk to your doctor, if your child is receiving any of the following:

- astemizole or terfenadine (for hay fever or allergy)
- cisapride (for stomach disorders)
- pimozone (for mental disorders)
- ergotamine or dihydroergotamine (for migraine)
- ticagrelor or ranolazine (for heart attack, chest pain or angina)
- colchicine (usually taken for gout)
- lovastatin, simvastatin or atorvastatin (treatments to lower cholesterol [a type of fat] in blood).

Also see section **‘Do not give Clarithromycin Oral Suspension, if your child’**.

Your doctor may need to control blood levels or effects, or adjust the dosage, or interrupt (for some time) the treatment, if Clarithromycin Oral Suspension is used at the same time with medicines containing one of the substances listed below:

- digoxin (for heart failure)
- quinidine or disopyramide (for heartbeat disorders)
- intravenous or oromucosal midazolam (sedatives/sleeping pills)
- triazolam (sleeping pills)
- alprazolam (for anxiety)
- verapamil, diltiazem or amlodipine (medicine against high blood pressure)
- tolterodine (medicine to treat urinary incontinence)
- St. John’s Wort (herbal product used for depression)
- cyclosporin, tacrolimus or sirolimus (help prevent rejection after a transplant)
- theophylline (used in patients with breathing difficulties such as asthma)
- etravirine, efavirenz, ritonavir, zidovudine, nevirapine, atazanavir or saquinavir (anti-viral drugs used in the treatment of HIV)
- rifampicin, rifabutin or rifapentine (antibiotics used in the treatment of certain bacterial infections)
- fluconazole, itraconazole (antifungal medicine)
- oral anticoagulants such as warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (blood thinner). Your child’s prothrombin time should be monitored frequently
- rosuvastatin (cholesterol-lowering drugs). Statins can cause rhabdomyolosis (a condition which causes the breakdown of muscle tissue which can result in kidney damage). Signs of myopathy (muscle pain or muscle weakness) should be monitored.
- phenytoin, carbamazepine, valproate or phenobarbital (for epilepsy)
- insulin or other diabetes medicines, e.g. repaglinide, nateglinide (used to lower blood glucose levels)
- gliclazide or glimepiride (sulphonylureas used in the treatment of type II diabetes)
- sildenafil, tadalafil and vardenafil (for impotence in adult males or for use in high blood pressure in the blood vessels of the lungs)
- cilostazol (for poor circulation)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- quetiapine or other antipsychotic medicines
- other macrolide medicines
- lincomycin and clindamycin (lincosamides – a type of antibiotic)
- hydroxychloroquine or chloroquine (medicines used to treat autoimmune diseases).

It may still be all right for your child to be given Clarithromycin Oral Suspension and your doctor will be able to decide what is suitable for your child.

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

### **Clarithromycin Oral Suspension with food and drink**

Clarithromycin Oral Suspension may be taken with or without food.

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

The safety of clarithromycin in pregnancy and breast-feeding is not known and it is not usually given during pregnancy or breastfeeding unless it is considered very necessary. As clarithromycin may be given to girls of childbearing age, you should speak to your doctor before giving this medicine if pregnancy is known or suspected.

### **Driving and using machines**

Clarithromycin is known to cause dizziness, vertigo, confusion, and disorientation. This may affect your child's ability to drive and use machines. Make sure you know how your child reacts to clarithromycin before he/she drives, uses machines, or engages in any other activity that could be dangerous if he/she is not alert.

### **Clarithromycin Oral Suspension contains sucrose**

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 Oral Suspension also contains aspartame**

Aspartame is a source of phenylalanine. It may be harmful for people with phenylketonuria.

## **3. How to give Clarithromycin Oral Suspension**

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

Do not give more than the doctor told you to. If you have any questions, please ask your doctor or pharmacist before you give clarithromycin to your child.

The dose of clarithromycin depends on your child's weight in kilograms and is usually approximately 7.5 mg for each kilogram body weight given twice each day, usually in the morning and in the evening. The suspension can be given with or without food.

Clarithromycin suspension is usually given for 5 to 10 days. Your doctor will tell you how long to give clarithromycin.

Clarithromycin Oral Suspension will be supplied with an oral dosing spoon or pipette (syringe) to help you measure the right amount of medicine to give to your child. Your doctor or pharmacist will advise you whether it is better to use the spoon or the pipette to give the right dose. Make sure that you are clear about this before you start to give the suspension.

The usual doses of Clarithromycin 125 mg/5 ml Oral Suspension to be given either with the spoon or with the pipette are shown below:

<b>Weight (kg)</b>	<b>Approximate Age (years)</b>	<b>Dose in millilitres of suspension (twice daily) using the pipette</b>	<b>Number of 5ml spoonfuls to be given twice daily</b>
8 - 11	1 - 2	2.5	½
12 - 19	3 - 6	5	1
20 - 29	7 - 9	7.5	1½
30 - 40	10 - 12	10	2

The usual doses of Clarithromycin 250 mg/5 ml Oral Suspension to be given either with the spoon or with the pipette are shown below:

<b>Weight (kg)</b>	<b>Approximate Age (years)</b>	<b>Dose in millilitres of suspension (twice daily) using the pipette</b>	<b>Number of 5ml spoonfuls to be given twice daily</b>
8 - 11	1 - 2	1.25	¼
12 - 19	3 - 6	2.5	½
20 - 29	7 - 9	3.75	¾
30 - 40	10 - 12	5.0	1

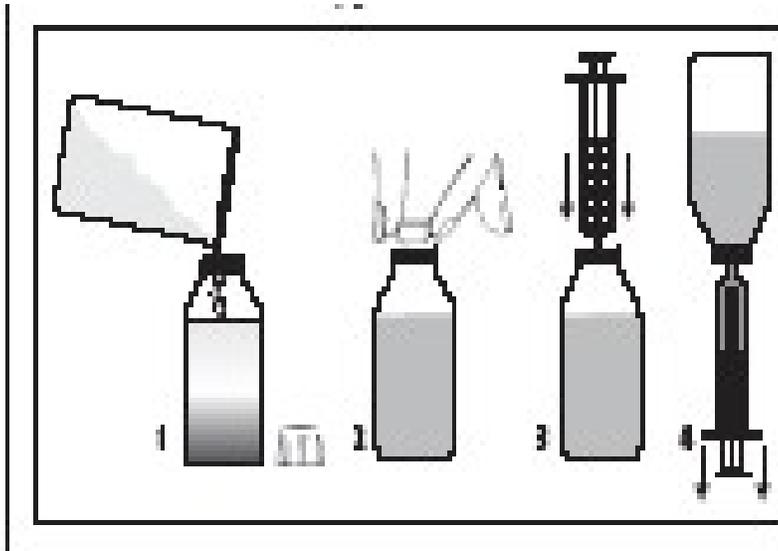
If your child weighs less than 8 kilograms, your doctor will calculate the dose for your child and this will be written on the pharmacist's label.

In the treatment of severe infections, doses up to 500 mg clarithromycin twice daily have been used.

Your doctor may prescribe a lower dose if your child has mild to moderate kidney or liver problems.

Clarithromycin Oral Suspension is supplied with an oral dosing spoon or pipette (syringe). If you use the pipette, please follow instructions given below carefully. After use of the spoon or syringe, wash in warm soapy water and rinse well.

1. 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 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 syringe into the hole in the adaptor.
5. Turn the bottle upside down. Keep hold of the bottle in one hand and the syringe in the other.
6. Hold the barrel of the 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 syringe from the adaptor.
8. Put the syringe tip into your baby'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 syringe onto a spoon for your child to take the medicine from.
9. Replace the cap on the bottle of the medicine.
10. Wash the syringe in warm soapy water and rinse well. Hold the syringe under water and move the plunger up and down several times to make sure the inside of the barrel is clean. Store the syringe in a hygienic place with the medicine.



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



**Administering the dose of the suspension**



**Administration of water or juice after medicine**

If you have the impression that the effect of clarithromycin suspension is too strong or too weak, talk to your doctor or pharmacist.

**If you give more Clarithromycin Oral Suspension than you should**

If your child has accidentally swallowed some extra medicine, consult your doctor or go to the nearest hospital emergency department immediately. Take this leaflet or bottle of suspension with you so the doctor will know what your child has taken. An overdose of Clarithromycin Oral Suspension is likely to cause vomiting and stomach pains.

**If you forget to give Clarithromycin Oral Suspension**

Give it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and give the next dose when it is due. Do not give a double dose to make up for a forgotten dose.

**If you stop giving Clarithromycin Oral Suspension**

Do not stop giving the suspension before your doctor tells you to, even if your child feels better, because the symptoms may return.

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 any of the following happens, stop using Clarithromycin Oral Suspension and tell your child's doctor immediately or go to the casualty department at your nearest hospital:

Uncommonly reported (may affect up to 1 in 100 people):

- any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching. This is a sign that your child may have developed an allergic reaction.

Frequency not known (frequency cannot be estimated from the available data):

- Contact a doctor immediately if you experience a serious skin reaction; a red scaly rash with bums under the skin and blisters (exanthematous pustulosis)
- severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis)
- severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur after the treatment with clarithromycin (see also **Warnings and precautions**).
- rash, fever, abnormal blood count and inflammation of internal organs. These may be symptoms of drug reaction with eosinophilia and systemic symptoms (DRESS).
- jaundice (yellowing of the skin or eyes), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These may be signs that your child's liver may not be working properly.

Tell your doctor immediately or go to the casualty department at your nearest hospital if any of the following happens:

Commonly reported (may affect up to 1 in 10 people):

- abnormal liver test results

Uncommonly reported (may affect up to 1 in 100 people):

- heart attack, dangerously fast heartbeat, ECG changes, extra heart beats, palpitations
- blood clot in the lungs which causes chest pain and breathlessness

Frequency not known (frequency cannot be estimated from the available data):

- changes in heartbeat rhythm (torsades de pointes), increased heart rate (tachycardia)
- inflammation of the pancreas (combined with severe pain in the upper abdominal region radiating to the back, along with nausea and vomiting)
- inflammation of kidneys (combined with blood in the urine, fever, and pain in the sides)
- hypoglycaemia (abnormally low blood sugar indicated by feeling hungry, sweating, dizziness, heart palpitation) particularly after taking anti-diabetic medicine, muscle weakness, tenderness or pain and particularly, if at the same time, your child feels unwell or has a high temperature it may be caused by an abnormal muscle breakdown, which can lead to kidney problems (rhabdomyolysis).

These side effects are serious. Your child may need medical attention.

**Other side effects**

Tell your doctor as soon as possible if your child develops any of the following:

Commonly reported (may affect up to 1 in 10 people):

- rash
- increased sweating (hyperhidrosis)
- widening of blood vessels
- sleeplessness (insomnia)
- headache
- feeling sick (nausea), vomiting, stomach pain, indigestion, diarrhoea
- change in the sense of taste, altered taste (for example metallic or bitter taste)

Uncommonly reported (may affect up to 1 in 100 people):

- inflammation of the skin with blisters (dermatitis bullous), itching of the skin, skin rash and hives (urticaria), rash characterized by a flat, red area on the skin that is covered with small confluent bumps (rash maculo-papular)
- cholestasis (bile disorder)
- hot, tender and red skin, sometimes with fever and chills (cellulitis)
- mild to severe nausea, vomiting, cramps, diarrhoea. These symptoms may be due to inflammation of the stomach and intestines, usually caused by a virus
- frequent infections such as fever, severe chills, sore throat or mouth ulcers. These symptoms may be due to low count of white blood cells
- increase in some white blood cells, increase platelet count (thrombocytopenia)
- raised blood urea nitrogen or creatinine (waste products)
- changed blood levels of albumin, globulin, and diverse enzymes (alkaline phosphatase, lactate dehydrogenase)
- loss of consciousness; uncontrollable twitching, jerking or writhing movements; drowsiness, shaking or tremors
- breathlessness, wheezing, a cough sometimes brought on by exercise, and a feeling of tightness in the chest (asthma), spinning sensation, hearing impaired, ringing in the ears (tinnitus)
- inflammation of the food pipe (oesophagitis), stomach (gastritis), in the mouth or the tongue
- a burning sensation in the chest rising up to the throat, also known as heartburn
- constipation, dry mouth, winds, abdominal distension, belching
- pain in the rectum
- fever, feeling of weakness, chest pain, chills, tiredness, muscle pain, muscle stiffness, muscle spasm, loss of muscle tissue
- decreased appetite, loss of appetite (anorexia)
- if your child suffers from myasthenia gravis (a condition in which the muscles become weak and tired easily), clarithromycin may worsen these symptoms
- anxiety, nervousness, dizziness, screaming
- generally feeling unwell

- infection of vagina
- thrush (fungal infection)
- nose bleed
- decrease in neutrophils (neutropenia)

Frequency not known (frequency cannot be estimated from the available data):

- inflammation of the colon
- abnormal urine colour
- bacterial infections of the skin (erysipelas)
- severely reduced kidney function (renal failure)
- deafness
- convulsions (fits)
- abnormally low counts of blood platelets (which may cause bruising of the skin or increased tendency to bleed)
- bleeding (haemorrhage)
- numbness and tingling in arms and legs (paraesthesia), tooth discoloration
- pain or weakness in muscles (myopathy)
- loss of taste functions of the tongue (ageusia), tongue discoloration
- inability to perceive smells, change in the sense of smell
- acne
- depression, hallucinations, abnormal thoughts (psychosis), not knowing where you are (disorientation), out of body feeling (depersonalization), bad dreams, confusion
- long bleeding and blood clotting time

**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](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 Oral Suspension**

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

Do not store above 25°C. Do not refrigerate or freeze. Keep the bottle tightly closed. Discard unused portion after 14 days or return to your pharmacist, who will dispose of it.

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 Oral Suspension contains**

Each 5 ml of the constituted suspension contains clarithromycin 125 mg or 250 mg.

The other ingredients are microcrystalline cellulose, hypromellose, hydroxypropyl cellulose, croscarmellose sodium, alginic acid, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30%, macrogol 1500, talc, carbomer (Carbopol 974 P), colloidal anhydrous silica, sucrose,

aspartame (E951), xanthan gum, monosodium citrate, sodium benzoate (E211), titanium dioxide (E171), sodium chloride, Peppermint and Tutti Frutti flavours.

**What Clarithromycin Oral Suspension looks like and contents of the pack**

Clarithromycin 125 mg/5 ml or 250 mg/5 ml Oral Suspension is white to off-white granular powder forming a white to off-white suspension on constitution with water. The resulting suspension has a sweet taste and fruity flavour.

The suspension is available in bottles of 50, 60, 70, 100 and 140 ml. Not all the pack sizes may be available.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

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