

KLARICID® PAEDIATRIC SUSPENSION

250MG/5ML

(Clarithromycin)



Read all of this leaflet carefully before you give this medicine to your child because it contains important information.

- 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 your child only. Do not pass it on to others. It may harm them, even if their symptoms 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 Klaricid Paediatric Suspension 250mg/5ml is and what it is used for
2. What you need to know before giving Klaricid Paediatric Suspension 250mg/5ml
3. How to give Klaricid Paediatric Suspension 250mg/5ml
4. Possible side effects
5. How to store Klaricid Paediatric Suspension 250mg/5ml
6. Contents of the pack and other information

1. What Klaricid Paediatric Suspension 250mg/5ml is and what it is used for

Each 5ml spoonful of Klaricid Paediatric Suspension 250mg/5ml contains 250mg of the active ingredient clarithromycin.

Klaricid belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) that cause infections.

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
4. Ear infections particularly inflammation of the middle ear (acute otitis media).

Klaricid Paediatric Suspension 250mg/5ml is used in children 6 months to 12 years old.

2. What you need to know before giving Klaricid Paediatric Suspension 250mg/5ml



Do not give Klaricid Paediatric Suspension 250mg/5ml to your child if they;

- are **allergic** to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients of Klaricid Paediatric Suspension 250mg/5ml.
- 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 pimozone (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 their blood (hypokalaemia).
- have **severe** liver disease with kidney disease.
- 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".
- are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina)
- are taking colchicine (usually taken for gout).

Warning and precautions

Talk to your doctor or pharmacist before giving Klaricid Paediatric Suspension 250mg/5ml:

- if your child has heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or abnormally low levels of magnesium in the blood(hypomagnesaemia)).
- 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 Klaricid paediatric Suspension 250mg/5ml

Your child should **not** take Klaricid Paediatric Suspension 250mg/5ml if they are taking any of the medicines listed in the section above "Do not give Klaricid Paediatric Suspension 250mg/5ml to your child if they;"

Tell your doctor if your child is taking 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)
- ibrutinib (for cancer treatment)
- 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 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.

Pregnancy and breast-feeding

The safety of Klaricid Paediatric Suspension 250mg/5ml in pregnancy and breast-feeding is not known. As Klaricid Paediatric Suspension 250mg/5ml may be given to girls of child-bearing age you should speak to your doctor before giving this medicine if pregnancy is known or suspected.

Driving and Using Machines:

Klaricid Paediatric Suspension may make you feel dizzy or drowsy. If they affect you or your child in this way do not drive, operate machinery or do anything that requires you to be alert.

Klaricid Paediatric Suspension 250mg/5ml contains sucrose

This medicine contains sucrose, which is a type of sugar. If your child has been told that they have an intolerance to any sugars, contact your doctor before your child takes this medicine.

3. How to give Klaricid Paediatric Suspension 250mg/5ml

Always give Klaricid Paediatric Suspension 250mg/5ml exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure how the dose has been worked out for your child.

The recommended doses of Klaricid Paediatric Suspension 250mg/5ml are given below:

Dosage based on body weight

Weight (kg)	Age (years)	Dosage in mls (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

Children who weigh less than 8kg should be given a dose of 0.15 ml/kg twice a day.

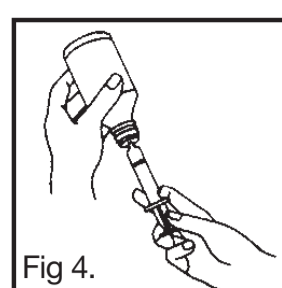
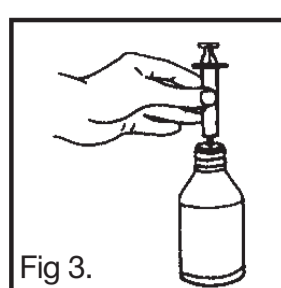
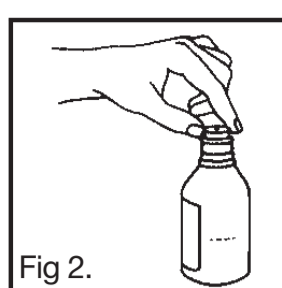
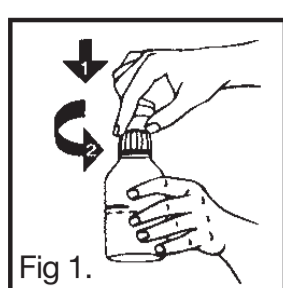
Doctors may sometimes prescribe higher or lower doses than these.

Klaricid Paediatric Suspension 250mg/5ml is supplied with a pipette to help you measure the right amount of medicine to give to your child. **Please follow these instructions carefully;**

1. Remove the child-proof cap from the bottle by pushing down on the cap while turning it anticlockwise (Fig 1).
2. Take the plastic circular stopper from the carton and push this into the neck of the bottle. This should fit tightly and once it is in the place it should not be removed. (Fig 2).
3. Take the pipette 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 pipette into the hole in the stopper (Fig 3).
5. Turn the bottle upside down. Keep hold of the bottle in one hand and the pipette in the other (Fig 4).
6. Hold the barrel of the pipette steady and slowly, pull the plunger down until you see the liquid fill the barrel to the mark which matches the number of ml that you need to give to your child (Fig 4).
7. Turn the bottle back the right way up.
8. Keeping hold of the barrel, remove the whole pipette from the bottle.
9. The contents of the pipette can be emptied directly into your child's mouth by pushing down on the plunger while still holding the barrel. Alternatively, empty the measured dose from the pipette onto a spoon for your child to take the medicine from.
10. Replace the cap on the bottle of medicine.

11. Wash the pipette in warm soapy water and rinse well. Hold the pipette under water and move the plunger up and down several times to make sure the inside of the barrel is clean.

Store the pipette in a hygienic place with the medicine.



Klaricid Paediatric Suspension 250mg/5ml 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.

You should shake the bottle well before using and replace the cap firmly after use. Klaricid Paediatric Suspension 250mg/5ml is usually given for 5 to 10 days.

If you give more Klaricid Paediatric Suspension 250mg/5ml than you should

If you accidentally give your child more Klaricid Paediatric Suspension 250mg/5ml 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 Klaricid Paediatric Suspension 250mg/5ml is likely to cause vomiting and stomach pains.

If you forget to give Klaricid Paediatric Suspension 250mg/5ml

If you forget to give your child a dose of medicine, give one as soon as you remember. Do not give more Klaricid Paediatric Suspension 250mg/5ml in one day than your doctor tells you to.

If you stop giving Klaricid Paediatric Suspension 250mg/5ml

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, Klaricid Paediatric Suspension 250mg/5ml can cause side effects although not everybody gets them.

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 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 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 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;

- 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 affect 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 your child suffers 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 more information on the safety of this medicine.

5. How to store Klaricid Paediatric Suspension 250mg/5ml



Keep this medicine out of sight and reach of children

Do not use this medicine after its use-by (exp.) date that is printed on the label. Keep this medicine in a cool place. Do not store above 30°C. Do not refrigerate or freeze.

Klaricid Paediatric Suspension 250mg/5ml must be used within 14 days of you receiving the bottle from the pharmacist.

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 protect the environment.

6. Contents of the pack and other Information

What Klaricid Paediatric Suspension 250mg/5ml contains

Each 5ml spoonful of Klaricid Paediatric Suspension 250mg/5ml contains 250 mg of the active ingredient clarithromycin.

Other ingredients are: sucrose, carbomers, povidone, hypromellose phthalate, castor oil (virgin), silicon dioxide, xanthan gum, fruit punch flavour, potassium sorbate, citric acid, maltodextrin and titanium dioxide.

What Klaricid Paediatric Suspension 250mg/5ml looks like and contents of the pack

Klaricid Paediatric Suspension 250mg/5ml is an off-white colour and is available in bottles of 70 ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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

Manufacturer - AbbVie S.r.l, S.R 148 Pontina KM 52 SNC, 04011 Campoverde di Aprilia (LT) Italy

This leaflet was last revised in March 2019.

Mylan

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