

PATIENT INFORMATION LEAFLET
ON
KLACID® PAEDIATRIC SUSPENSION 125MG/5ML,
GRANULES FOR ORAL SUSPENSION
(clarithromycin)



Read all of this leaflet carefully before you give this medicine to your child.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Klacid Paediatric Suspension is and what it is used for
2. Before giving Klacid Paediatric Suspension
3. Giving Klacid Paediatric Suspension
4. Possible side effects
5. How to store Klacid Paediatric Suspension
6. Contents of the pack and other information

1. What Klacid Paediatric Suspension is and what it is used for

Each 5ml spoonful of Klacid Paediatric Suspension contains 125 mg of the active ingredient clarithromycin.

Klacid Paediatric Suspension belongs to a group of medicines called macrolide antibiotics.

Antibiotics stop the growth of bacteria (bugs) which cause infections.

Klacid Paediatric Suspension is used to treat infections such as:

1. Chest infections, such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and soft tissue infections such as cellulitis, folliculitis or erysipelas
4. Ear infections particularly inflammation of the middle ear (acute otitis media)

2. Before giving Klacid Paediatric Suspension



Do not give Klacid Paediatric Suspension to your child if you:

- know that they are allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients of Klacid Paediatric Suspension.
- know they are taking medicines called ergot alkaloids, for example ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine. Consult your doctor for advice on alternative medicines.
- know they are taking medicines called simvastatin or lovastatin (used to lower increased blood fats such as cholesterol and triglycerides).
- know they are taking medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride or pimozide tablets as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- know they are taking other medicines which are known to cause serious disturbances in heart rhythm
- know they are taking medicines called ticagrelor or ranolazine (for angina or to reduce the chance of heart attack or stroke)
- know they are taking a medicine called colchicine.
- know that they have abnormally low levels of potassium in their blood (hypokalaemia).
- know they are taking oral midazolam (for epilepsy).
- know that they have any liver and/or kidney problems.
- know that they or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or an abnormality of electrocardiogram (ECG, electrical recording of the heart) called "long QT syndrome".

Take special care with Klacid Paediatric Suspension;

- if your child has heart problems
- if your child needs to have intravenous or oromucosal (absorbed in the mouth) midazolam
- if your child has abnormally low levels of magnesium in their blood (hypomagnesaemia)

If any of these apply to your child, consult your doctor before giving them this medicine.

If your child develops severe or prolonged diarrhoea during or after receiving Klacid Paediatric Suspension, tell your doctor **immediately**, as this could be a symptom of more serious conditions such as pseudomembranous colitis or clostridium difficile associated diarrhoea.

If your child develops any symptoms of liver dysfunction such as anorexia (loss of appetite), yellowing of the skin or whites of the eyes, dark urine, itching or tender abdomen, stop giving Klacid Paediatric Suspension and tell your doctor **immediately**.

Long term use of Klacid Paediatric Suspension may lead to infection with resistant bacteria and fungi.

Klacid Paediatric Suspension contains 2.75g sucrose per 5ml. This should be taken into account in children with diabetes mellitus.

If your child has been told that they have an intolerance to any sugars, contact your doctor before giving them this medicine.

Taking other medicines

Please tell your doctor or pharmacist if your child is taking, or has recently taken, any other medicines, including those obtained without a prescription.

This is especially important if your child is taking medicines called:

- digoxin, quinidine or disopyramide (used to treat heart problems). Your child's heart may need to be monitored (ECG test) or blood tests may be needed if your child takes clarithromycin with some medicines used to treat heart problems
- warfarin, or any other anticoagulant (used to thin your child's blood). It may be necessary to have blood tests to check that your child's blood is clotting efficiently
- omeprazole (used for the treatment of indigestion and stomach ulcers) unless your doctor has prescribed it to treat Helicobacter pylori infection associated with duodenal ulcer
- ergot alkaloids such as ergotamine or dihydroergotamine (for the treatment of migraine)
- colchicine (for the treatment of gout). Your doctor may wish to monitor your child
- theophylline (used in patients with breathing difficulties such as asthma)
- terfenadine or astemizole (for hay fever or allergy)
- triazolam, alprazolam or midazolam (sedatives)
- cilostazol (for poor circulation)
- cisapride (for stomach disorders)
- carbamazepine, valproate, phenytoin or phenobarbital (for the treatment of epilepsy)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- ciclosporin, tacrolimus or sirolimus (immune suppressants used for organ transplants and severe eczema)
- pimozide or St. John's wort (for mental health problems)
- rifabutin, rifampicin, rifapentine, fluconazole and itraconazole (treatments for infectious diseases)
- verapamil, amlodipine or diltiazem (for high blood pressure)
- tolterodine (for overactive bladder)
- simvastatin and lovastatin (known as HMG-CoA reductase inhibitors for the treatment of high cholesterol)
- ritonavir, efavirenz, nevirapine, atazanavir, saquinavir, etravirine and zidovudine (anti-viral or anti-HIV drugs)
- 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)
- insulin, repaglinide or nateglinide (medicines for the treatment of diabetes)
- quetiapine or other antipsychotic medicines

Pregnancy and breast-feeding

The safety of Klacid Paediatric Suspension in pregnancy and breast-feeding is not known. As Klacid Paediatric Suspension may be given to girls of child-bearing age you should speak to your doctor before giving this product if you know or think your child is pregnant.

Driving and operating machinery

Klacid Paediatric Suspension may cause dizziness, vertigo, confusion and disorientation. If the patient is affected they should not drive or use machines.

3. Giving Klacid Paediatric Suspension

Always give Klacid Paediatric Suspension exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure how the dose has been worked out for your child.

The usual doses of Klacid Paediatric Suspension are given below:

Dosage based on Body Weight (kg)

Weight* (kg)	Approx. Age (yrs)	Klacid Paediatric Suspension (dosage in millilitres given twice daily by pipette or spoon)
8-11	1-2	2.5ml (1/2 spoonful)
12-19	3-6	5ml (1 spoonful)
20-29	7-9	7.5ml (1 1/2 spoonful)
30-40	10-12	10ml (2 spoonfuls)

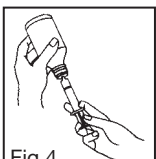
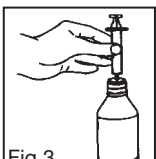
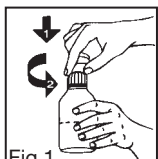
* Children who weigh less than 8kg should be given a dose of 0.3 ml/kg twice a day.

Doctors may sometimes prescribe higher or lower doses than these. If this applies to your child then you should discuss it with your doctor or pharmacist.

Due to the smaller quantities of medicine required for dosing of Klacid Paediatric Suspension, this medicine 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. Shake the bottle well but avoid vigorous and/or lengthy shaking. Shake before each subsequent use to ensure resuspension.
2. Remove the child-proof cap from the bottle by pushing down on the cap while turning it anticlockwise (Fig 1).
3. 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 place it should not be removed (Fig 2).
4. 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.
5. Insert the nozzle of the pipette into the hole in the stopper (Fig 3).
6. Turn the bottle upside down. Keep hold of the bottle in one hand and the pipette in the other (Fig 4).
7. 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).
8. Turn the bottle back the right way up.
9. Keeping hold of the barrel, remove the whole pipette from the bottle.
10. 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.
11. Replace the cap on the bottle of medicine.
12. 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.



Klacid Paediatric Suspension 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.

Klacid Paediatric Suspension is usually given for 5 to 10 days.

If you give more Klacid Paediatric Suspension than you should

If you accidentally give your child more Klacid Paediatric Suspension 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 Klacid Paediatric Suspension is likely to cause vomiting and stomach pains.

If you forget to give Klacid Paediatric Suspension

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

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.

4. Possible side effects



Like all medicines, Klacid Paediatric Suspension can cause side effects although not everybody gets them.

If your child develops severe or prolonged diarrhoea, which may have blood or mucus in it, during or after being given Klacid Paediatric Suspension, consult your doctor immediately, as these could be symptoms of more serious conditions such as pseudomembranous colitis or clostridium difficile associated diarrhoea. Diarrhoea may occur over two months after treatment with clarithromycin.

If your child develops a rash, difficulty breathing, fainting or swelling of the face and throat, contact your doctor immediately as these may be signs of an allergic reaction and may need emergency treatment.

If your child develops loss of appetite, yellowing of the skin (jaundice), dark urine, itching or tenderness in the abdomen, contact your doctor immediately as these may be signs of liver failure.

Other side effects of Klacid (all formulations) may include:

Very common (affects more than 1 user in 10):

- inflammation of a vein (phlebitis) at the site of injection (Klacid IV)

Common (affects 1 to 10 users in 100):

- difficulty sleeping (insomnia)
- changes in sense of taste
- headache
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- abnormal liver function blood tests
- rash, excessive sweating, flushing
- pain or inflammation at the site of injection (Klacid IV)

Uncommon (affects 1 to 10 users in 1000):

- infections of the skin or vagina, yeast infections (thrush)
- change in the level of white blood cells in the blood (which can make infections more likely)
- change in the levels of blood platelets in the blood (increased risk of bruising, bleeding or blood clots)
- allergic reaction
- anorexia, decreased appetite
- anxiety, nervousness
- fainting, dizziness, drowsiness, tremor, involuntary movements of the tongue, face, lips or limbs
- spinning sensation (vertigo), ringing in the ears, hearing loss
- fast, pounding heart (palpitations), changes in heart rhythm or heart stopping
- breathing problems (asthma), nosebleed
- blood clot in the lungs
- stomach problems such as bloating, constipation, wind (flatulence), belching, heartburn or anal pain,
- inflammation of the lining of the stomach or oesophagus (the tube connecting your mouth with your stomach)
- sore mouth, dry mouth, inflammation of the tongue
- liver problems such as hepatitis or cholestasis which may cause yellowing of the skin (jaundice), pale stools or dark urine

- increase in liver enzymes
- itching, hives, inflammation of the skin
- stiffness, aches or spasms in the muscles
- kidney problems such as raised levels of protein normally excreted by the kidneys or raised levels of kidney enzymes
- fever, chills, weakness, fatigue, chest pain or general feeling of discomfort
- abnormal blood test results

Not known (frequency cannot be estimated from available data):

- infection of the colon
- infection of the skin
- swelling of the skin around the face and the throat. This may cause difficulty in breathing (angioedema)
- psychotic disorder, confusion, change in sense of reality, depression, loss of bearings (disorientation), hallucinations (seeing things), abnormal dreams (nightmares), manic episodes.
- convulsions
- changes or loss in sense of taste and/or smell
- paraesthesia (tingling and burning sensation in the skin, numbness, ‘pins and needles’ sensation)
- deafness
- bleeding
- inflammation of the pancreas
- discoloration of the tongue, tooth discolouration
- liver failure, jaundice (yellowing of the skin)
- rare allergic skin reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis (which cause severe illness with ulceration of the mouth, lips and skin), DRESS (which causes severe illness with rash, fever and inflammation of internal organs)
- acne
- muscle disease (myopathy), breakdown of muscle tissue (rhabdomyolysis)
- inflammation of the kidney (which can cause swollen ankles or high blood pressure) or kidney failure

Consult your doctor immediately if your child develops any of these problems or has any other unexpected or unusual symptoms.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Klacid Paediatric Suspension

Keep out of the reach and sight of children.

Do not use this medicine after its use-by (expiry) date which is printed on the label. The expiry date refers to the last day of the month.

Do not store above 25°C. Do not refrigerate.

Klacid Paediatric Suspension must be used within 14 days of you receiving the bottle from the pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Klacid Paediatric Suspension contains

Each 5ml spoonful of Klacid Paediatric Suspension contains 125 mg of the active ingredient clarithromycin.

The other ingredients are; sucrose, carbomers (carbopol 974P), povidone K90, hypromellose phthalate, castor oil, silicon dioxide, xanthan gum, fruit punch flavour, potassium sorbate, citric acid, maltodextrin, titanium dioxide and water.

What Klacid Paediatric Suspension looks like and contents of the pack

Klacid Paediatric Suspension is a granules for oral suspension product. Klacid Paediatric Suspension is an off-white colour and is fruit-punch flavoured. It is available in bottles of 50ml, 70ml, 100ml and 140ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Mylan IRE Healthcare Limited,

Unit 35/36, Grange Parade,

Baldoyle Industrial Estate,

Dublin 13.

Manufacturer:

AbbVie S.r.l.

S.R. 148 Pontina km 52 snc

04011 Campoverde di Aprilia (LT)

Italy

This leaflet applies only to Klacid Paediatric Suspension 125mg/5ml, Granules for Oral Suspension.

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