4. Possible side effects

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

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

• 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.

• Keep this leaflet. You may need to read it again.

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

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:

• chest infections, such as bronchitis and pneumonia
• skin and tissue infections
• ear infections
• urinary tract infections
• hives (urticaria)
• tonsillitis

The active ingredient clarithromycin.

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

• are taking any of the medicines listed in the section above

If your child has, or is prone to, fungal infections (e.g. thrush)

• are taking midazolam (a sedative)

Your child should not be given Klaricid Paediatric Suspension 250mg/5ml if they:

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

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

These medicines are called macrolides and can cause serious damage to heart muscle.

• if your child has heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or abnormal levels of magnesium in the blood)

• if you are pregnant, breast-feeding or planning to become pregnant

• if your child has an intolerance to any sugars, contact your doctor before your child takes this medicine. This medicine contains sucrose, which is a type of sugar. If your child has been told that they should avoid all foods or drinks containing sucrose, they should not use this medicine.

• if you or your child have, or are prone to, intolerance to barbiturate medicines (e.g. phenobarbital, secobarbital, phenytoin or phenobarbital). This medicine contains secobarbital.

• have ever been treated with ritonavir with indinavir

• if you or your child have, or are prone to, intolerance to any of the medicines listed in the section above a known or suspected.

Driving and Using Machines

• if you are taking lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins) to lower your blood cholesterol level.

• if your child has, or is prone to, fungal infections (e.g. thrush)

• are taking oral midazolam (a sedative)

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. Push down on the cap of the bottle to remove the pipette (Fig 2). The pipette contains an amount of medicine which, when added to water, will make the right amount of medicine to give to your child in this way do not drive, operate machinery or do anything that requires you to be alert.

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

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Driving and Using Machines

• if you or your child have, or are prone to, intolerance to any sugars, contact your doctor before your child takes this medicine.

1. During or at the end of treatment

2. After treatment

3. Skin and tissue infections

4. Insert the nozzle of the pipette into the hole in the stopper (Fig 3).

5. Hold the barrel of the pipette steady and slowly, pull the plunger down until you see the medicine come out of the pipette (Fig 4). A pipette filler can be used to hold the pipette steady (Fig 5). The medicine should come out of the pipette with a gentle hiss as it falls down the hole in the stopper. If there is a lot of air in the pipette, it will make a loud sound as the medicine comes out of the pipette. If this happens, give the dose a second time and then give the correct dose (Fig 5).

6. Turn the bottle upside down. Keep the bottle of the pipette in one hand and the pipette upside down in the other hand (Fig 4).

7. Put the pipette into the bottle and turn it clockwise (Fig 6).

8. Keeping hold of the barrel, remove the whole pipette from the bottle. The medicine should still be in the pipette. If it is not, give the dose a second time and then give the correct dose (Fig 7).

9. The contents of the pipette can be emptied directly into your child’s mouth by pushing down on the pipette while it is held upright. If you or your child find this difficult, you can put the pipette in a cup and then pour the medicine from the pipette into the cup. The pipette can be rinsed out with water before you put it into the cup (Fig 8).

10. Replace the cap on the bottle of the medicine. Cover the bottle of the pipette with an appropriately sized cap to close it (Fig 9).

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

Drugs on or before body weight

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Age (years)</th>
<th>Dosage in ml (daily dose)</th>
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<td>3-6</td>
<td>2.5</td>
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<tr>
<td>8-11</td>
<td>1-2</td>
<td>1.25</td>
</tr>
<tr>
<td>5-7</td>
<td>0.5-1</td>
<td>0.625</td>
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Children who weigh less than 5kg should be given a dose of 0.15mg/kg each day.

Doctors sometimes prescribe a dose of 20-29mg/kg each day.

Klaricid Paediatric Suspension 250mg/5ml is supplied in a bottle containing 15ml of suspension medicated with sucrose.

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Doctors sometimes prescribe a dose of 20-29mg/kg each day.
If you give more Klaricid Paediatric Suspension 250mg/5ml than your doctor has told you to, or if your child accidentally swallows some extra medicine, Paediatric Suspension 250mg/5ml is usually given for 5 to 10 days. You should shake the bottle well before using and replace the cap firmly after use. Klaricid Paediatric Suspension 250mg/5ml should be given twice a day, once in the morning and once in the evening, and should be taken with food. It can be given at mealtimes if this is more convenient.

Klaricid Paediatric Suspension 250mg/5ml is likely to cause vomiting and stomach pain. If you forget to give Klaricid Paediatric Suspension 250mg/5ml Do not give more Klaricid Paediatric Suspension 250mg/5ml in one day than your doctor has told you to, otherwise the problem might come back.

If you give Klaricid Paediatric Suspension 250mg/5ml to any other person, especially a child, contact your doctor immediately. You should take it for as long as your doctor has told you to, otherwise the problem might come back. If you stop giving Klaricid Paediatric Suspension 250mg/5ml Do not give 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, Your child should not give Klaricid Paediatric Suspension 250mg/5ml to any other person, especially a child, without consulting your doctor.

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects although not everybody gets them.

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

If your child suffers from any of the following at any time during their treatment STOP giving the medicine and contact your doctor immediately: muscle pain or loss of muscle tissue. If your child suffers from any of the following at any time during their treatment STOP giving the medicine and contact your doctor immediately: muscle spasms, muscle pain or loss of muscle tissue. If your child suffers from any of the following at any time during their treatment STOP giving the medicine and contact your doctor immediately: asthma: lung disease associated with tightening of air passages, making breathing difficult, chest pain or changes in heart rhythm such as palpitations or an irregular heartbeat. Other side effects

3. What are the ingredients of Klaricid Paediatric Suspension 250mg/5ml

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

Other ingredients are: sucrose, carbomers, povidone, hypromellose phthalate, castor oil maltodextrin and titanium dioxide.

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.

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

What Klaricid Paediatric Suspension 250mg/5ml contains

Klaricid Paediatric Suspension 250mg/5ml is used to treat chest infections and some other infections. Klaricid Paediatric Suspension 250mg/5ml contains a low concentration of the active ingredient clarithromycin and is suitable for children.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Mylan Products Ltd., 20 Station Close, Potters Bar, Hertfordshire, EN6 3JN, UK.

Marketing Authorisation Holder - Manufacturer:

Mylan Products Ltd., 20 Station Close, Potters Bar, Hertfordshire, EN6 3JN, UK.

Manufacture - Mylan Europe S.r.l., S-158-1492 Pratunam 54, 52110 Capriavalle, Italy

This leaflet was last revised in May 2020.