

PACKAGE LEAFLET: INFORMATION FOR THE USER

Levocarnitine Paediatric 30% Oral Solution (levocarnitine 30% w/v)

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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 get serious, or you notice any side effects not listed in this leaflet please tell your doctor or pharmacist
- In this leaflet Levocarnitine Paediatric 30% Oral Solution will be called Levocarnitine paediatric.

In this leaflet

1. What Levocarnitine paediatric is and what it is used for
2. Before you give your child Levocarnitine paediatric
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1. What Levocarnitine paediatric is and what it is used for

Levocarnitine paediatric contains levocarnitine which is a type of protein. It is used to treat primary and secondary levocarnitine deficiency in children less than 12 years of age, infants and newborns. Carnitine deficiency occurs when the body has a shortage of levocarnitine. Levocarnitine paediatric makes up for the body's lack of levocarnitine and helps give the body more energy.

2. Before you give your child Levocarnitine paediatric

Do not give your child Levocarnitine paediatric:

- if your child is allergic to levocarnitine or any other ingredients in Levocarnitine paediatric . These ingredients are listed in section 6 of this leaflet.

If this applies to your child, do not give them Levocarnitine paediatric.

Tell your doctor before you give your child Levocarnitine paediatric if:

- your child has severe kidney problems or kidney disease and is having dialysis
- your child is diabetic and taking insulin, or any other drug to treat their diabetes
- your child is a diabetic or is on a diet to reduce calorie intake
- your child is taking anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting
- your child has an intolerance to some sugars.

If any of the above apply to your child, talk to your doctor or pharmacist.

Taking other medicines

Tell your doctor if your child is taking anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting. Your doctor may need to change how often your child is tested to see how fast their blood clots.

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

Important information about some of the ingredients of Levocarnitine paediatric

This product contains sorbitol solution which can cause stomach upsets and diarrhoea when taken in large doses. This product contains sucrose. If you have been told by the doctor that your child has an intolerance to some sugars, contact your doctor before giving your child this medicine. It also contains methyl hydroxybenzoate (E217) and propyl hydroxybenzoate (E219) which may cause immediate or delayed allergic reactions.

3. How to give your child Levocarnitine paediatric

Always give your child Levocarnitine paediatric exactly as your doctor has told you.

How much Levocarnitine paediatric should you give to your child

Your doctor will carefully calculate the amount of Levocarnitine paediatric that your child should take and may vary it depending on their response to the treatment. Your doctor may take blood and urine samples to check the amount of the drug in your child's body.

Method of administration

Levocarnitine paediatric is for oral use. It can be drunk directly or diluted further with water or fruit juices.

Primary and secondary carnitine deficiency

The usual dose of Levocarnitine paediatric is up to 200 mg per kg of your child's bodyweight per day. This should be taken over 2-4 doses. Higher doses of up to 400 mg per kg of bodyweight per day may be necessary. Your doctor will tell you exactly how much medicine to give your child and when to give it.

If you give your child more Levocarnitine paediatric than you should

If you give your child too much Levocarnitine paediatric, contact your doctor or immediately go to the nearest hospital casualty department.

If you forget to give your child Levocarnitine paediatric

Do not give your child a double dose to make up for a forgotten dose. Simply continue with the next dose as planned.

If your child stops taking Levocarnitine paediatric

Do not stop giving your child this medicine without first talking to your doctor.

If you have any further questions about giving your child this medicine, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Levocarnitine paediatric can cause side effects, although not everybody gets them.

Side effects are:

- Mild stomach upsets such as stomach cramps or diarrhoea, or your child may feel or be sick for a short time
- Drug-related body odour. Your doctor may reduce your child's dose to help lessen or stop the odour.
- For children also taking anticoagulant medicine, such as warfarin, tests may show their blood is taking longer than usual to clot.

Reporting of side effects

If your child gets 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levocarnitine paediatric

Keep out of the reach and the sight of children.

Do not use Levocarnitine paediatric after the expiry date stated on the amber glass bottle. The expiry date refers to the last day of that month.

Store below 25°C. Protect from light and moisture.

Medicines should not be thrown away in waste water or in household waste. Return any medicine you no longer need to the pharmacist.

6. Further information

- The active substance is levocarnitine. Levocarnitine paediatric contains 30% w/v levocarnitine in each 20 ml amber glass bottle.
- The other ingredients are sobitol solution (70%)(E420), tartaric acid (E334), sodium propyl hydroxybenzoate (E217), sodium methyl hydroxybenzoate (E219), colourless cherry flavour, colourless sour black cherry flavour, sucrose and purified water.

What Levocarnitine paediatric looks like and contents of the pack

Levocarnitine paediatric is a colourless or slightly yellow solution. It comes in 20 ml amber glass bottles with plastic child proof caps.

Marketing Authorisation Holder

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