

PACKAGE LEAFLET: Information for the user

Levocarnitine Paediatric 30% Oral Solution

(levocarnitine 30% w/v (300mg/ml)

Sugar Free/Alcohol Free

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 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 effect not listed in this leaflet. See section 4.
- In this leaflet Levocarnitine Paediatric 30% Oral Solution will be called Levocarnitine paediatric.

What is in this leaflet

1. What Levocarnitine paediatric is and what it is used for
2. What you need to know before you give your child Levocarnitine paediatric
3. How to give your child Levocarnitine paediatric
4. Possible side effects
5. How to store Levocarnitine paediatric
6. Contents of the pack and other information

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.

Levocarnitine 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. What you need to know before you give your child Levocarnitine paediatric

Do not give your child Levocarnitine paediatric:

- if your child is allergic to levocarnitine or any of the other ingredients in this medicine (listed in section 6).

Warnings and Precautions

Talk to 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 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.

Other medicines and Levocarnitine paediatric

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.

Levocarnitine paediatric contains sorbitol solution (E420), sodium methylhydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217).

This medicine contains 200mg of 70% sorbitol solution in each 2ml dose which is equivalent to 100 mg/ml

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive 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. Check with your doctor if you are not sure.

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.

Very rare side effects (may affect up to 1 in 10,000 people) 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 - Website: 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 Levocarnitine paediatric

Keep this medicine out of the sight and reach 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. Discard any medicine remaining 30 days after first opening the bottle.

Do not throw away any medicines via waste water or in 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 Levocarnitine paediatric contains

- The active substance is levocarnitine. Levocarnitine paediatric contains 30% w/v (300mg/ml) levocarnitine in each 20 ml, 40ml and 50ml amber glass bottle.
- The other ingredients are sorbitol solution (E420), sodium methyl hydroxybenzoate (E219) and sodium propyl hydroxybenzoate (E217), purified water and hydrochloric acid, concentrated (E507).

What Levocarnitine paediatric looks like and contents of the pack

Levocarnitine paediatric is a clear yellowish solution. It comes in 20 ml, 40ml and 50ml amber glass bottles with plastic polyethylene-polypropylene child-proof caps and a graduated dosage pipette, along with the patient information leaflet.

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