

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 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 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. In this leaflet Levocarnitine Paediatric 30% Oral Solution will be called Levocarnitine Paediatric Solution.

What is in this leaflet

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

1. What Levocarnitine Paediatric Solution is and what it is used for

Levocarnitine Paediatric Solution 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 Solution 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 Solution

Do not give your child Levocarnitine Paediatric Solution:

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

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

Warnings and precautions

Talk to your doctor before giving your child Levocarnitine Paediatric Solution 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 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.

Other medicines and Levocarnitine Paediatric Solution

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any 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.

Levocarnitine Paediatric Solution contains sorbitol, sucrose, sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217) and sodium

This product contains 100mg sorbitol in each ml of solution. Sorbitol is a source of fructose. If your doctor has told 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.

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 medicinal product.

Levocarnitine Paediatric Solution contains sodium methylhydroxybenzoate (E219) and sodium propylhydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1mmol sodium (23mg) per 1ml of oral solution, that is to say essentially "sodium-free".

3. How to give your child Levocarnitine Paediatric Solution

Always give your child this medicine exactly as your doctor has told you.

How much Levocarnitine Paediatric Solution should you give to your child

Your doctor will carefully calculate the amount of Levocarnitine Paediatric Solution 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 Solution 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 Solution is up to 200mg per kg of your child's bodyweight per day. This should be taken over 2-4 doses. Higher doses of up to 400mg 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 Solution than you should

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

If you forget to give your child Levocarnitine Paediatric Solution

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 Solution

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 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 Solution

- **Keep out of the sight and reach of children.**
- Do not use Levocarnitine Paediatric Solution after the expiry date printed on the carton label and the bottle label. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep bottle in the outer carton in order to protect from light and moisture.
- If your medicine becomes discoloured or shows signs of deterioration, you should seek the advice of your pharmacist.
- If your doctor decides to stop your treatment, take any leftover medicine back to the pharmacy.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. Content of the pack and other information

What Levocarnitine Paediatric Solution contains

- The active substance is levocarnitine. Each ml contains 300mg levocarnitine.
- The other ingredients are: sucrose, sorbitol, tartaric acid, sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), cherry flavour, black cherry flavour and purified water.

What Levocarnitine Paediatric Solution looks like and contents of the pack

Levocarnitine Paediatric Solution is a colourless or slightly yellow solution with cherry aroma.

Your medicine is available in 40ml amber glass bottle with plastic child proof cap.

Manufacturer

Manufactured by:
Alfasigma S.p.A., Via Pontina,
Km. 30,400-00071 Pomezia (Rome), Italy.
or
Pharmaloop, S.L., Poligono Industrial Azque c/ Bolivia, 15,
28806 Alcala de Henares (Madrid), Spain.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall,
Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharma Limited,
Crompton Road, Doncaster, DN2 4PW, UK

PL: 56830/0012

POM

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Blind or partially sighted?
Is this leaflet hard to see or
read?

Call +44 (0) 1302 365000
(Regulatory)

Please be ready to give the
following information:

Product name:

Levocarnitine Paediatric

30% Oral Solution

Reference No: 56830/0012