

Carnitor® Paediatric 30% Oral Solution

(levocarnitine)

2969
15.11.22[8]

PATIENT INFORMATION LEAFLET

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 Carnitor Paediatric 30% Oral Solution will be called Carnitor paediatric.

What is in this leaflet:

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

1. WHAT CARNITOR PAEDIATRIC IS AND WHAT IT IS USED FOR

Carnitor 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 CARNITOR PAEDIATRIC

Do not give your child Carnitor paediatric:

- if your child is allergic to levocarnitine or any other ingredients of this medicine (listed in section 6).
- If this applies to your child, do not give them Carnitor paediatric.

Warnings and precautions

Talk to your doctor before giving your child Carnitor 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 medicines, 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 Carnitor paediatric

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.

Carnitor paediatric contains sorbitol, sucrose, sodium methyl hydroxybenzoate (E217), sodium propyl hydroxybenzoate (E219) and sodium

This product contains 100 mg 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.

Carnitor paediatric contains sodium methyl hydroxybenzoate (E217) and sodium propyl hydroxybenzoate (E219) which may cause allergic reactions (possibly delayed).

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

3. HOW TO GIVE YOUR CHILD CARNITOR PAEDIATRIC

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

How much Carnitor paediatric should you give to your child

Your doctor will carefully calculate the amount of Carnitor 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

Carnitor 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 Carnitor 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 Carnitor paediatric than you should

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

If you forget to give your child Carnitor 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 Carnitor paediatric

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, please 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 an 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 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 CARNITOR PAEDIATRIC

- Keep out of the sight and reach of children.
- Do not store above 25°C. Keep bottle in the outer carton in order to protect from light and moisture.
- Do not use Carnitor paediatric after the expiry date stated on the amber glass bottle. The expiry date refers to the last day of that month.
- If your medicines show any sign of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be thrown away in waste water or in household waste. Return any medicine you no longer need to the pharmacist.

6. CONTENTS OF PACK AND OTHER INFORMATION

What Carnitor paediatric contains

The active substance is levocarnitine.
Each 1 ml contains 300 mg levocarnitine.

Also includes sucrose, sorbitol (E420), sodium propyl hydroxybenzoate (E217), sodium methyl hydroxybenzoate (E219), tartaric acid, cherry flavour (contains ethanol), black cherry flavour (contains ethanol) and purified water.

What Carnitor paediatric looks like and contents of the pack

Carnitor paediatric is a colourless or slightly yellow solution with a cherry aroma.

Available in a 40 ml amber glass bottle with plastic child proof caps and a 3.3 ml measuring spoon.

Manufacturer and product licence holder

Carnitor paediatric is manufactured by
Pharmaloop, S.L., Poligono Industrial Azque c/Bolivia 15, 28806 Alacala de
Henaraes, Madrid, Spain.
Alfasigma S.p.A., Via Pontina Km. 30, 400-00071 Pomezia, Italy.

Procured from within the EU by product licence holder Star Pharmaceuticals
Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by
Servipharm Ltd.

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S.p.A.

**Blind or partially sighted?
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leaflet in a format suitable for you.**

Levocarnitine Paediatric

30% Oral Solution

(levocarnitine)

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- 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. Content 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 other ingredients of this medicine (listed in section 6).

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Warnings and precautions

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- 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,
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