

Package leaflet: Information for the user

Levocarnitine Paediatric 30 % oral solution (levocarnitine) Sugar Free/Alcohol Free

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for them.

- 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 only. 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 effects 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 of 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.
- is diabetic and taking insulin, or any other drug to treat their diabetes.
- is taking anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting.
- 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, has recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

As this medicine is used to treat children less than 12 years of age, infants and newborns, the information is not necessary for Levocarnitine Paediatric.

Levocarnitine Paediatric contains sorbitol (E420), sodium methyl parahydroxybenzoate (E219) and sodium

This medicine contains 52.5 mg sorbitol in each ml of solution. Sorbitol is a source of fructose. If your doctor has told you that your child has an intolerance to some sugars or if your child has been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before your child receives this medicine.

Sorbitol does not cause dental caries and this product can be considered as sugar-free.

This medicine contains approximately 1.5 mg sodium methyl parahydroxybenzoate in each ml of solution and may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). It may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to give your child Levocarnitine Paediatric

Always give your child this medicine 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.

Administration and instructions for use

Levocarnitine Paediatric is for oral use.

Carefully measure the dose your doctor has told you to take using the provided dosing syringe and bottle adaptor.

1. Open the bottle: Press downward on the cap and turn it counter-clockwise (Figure 1).
2. **First time use only:** A bottle adaptor is provided with the oral syringe. This is the device that gets inserted into the neck of the bottle to make it easier to withdraw the solution using the

oral syringe. With the bottle on a flat surface, insert the bottle adaptor into the bottle neck while keeping the bottle adaptor's flat surface facing up and pressing on it (Figure 2).



Figure 1

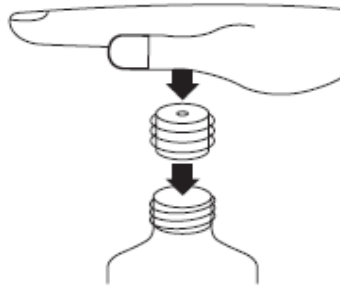


Figure 2

3. Push the syringe plunger to the bottom of the barrel of the syringe (toward its tip) to remove excess air. Attach the syringe to the bottle adaptor with a slight twisting motion (Figure 3).
4. Invert the bottle (with the syringe attached) and fill the syringe with the liquid by pulling the syringe plunger down to just beyond the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 4). Remove air bubbles from the syringe by pushing the plunger up to the appropriate graduation mark.
5. Return the bottle to an upright position with the syringe still in the bottle adaptor / bottle (Figure 5).
6. Remove the syringe from the bottle / bottle adaptor (Figure 6).



Figure 3



Figure 4

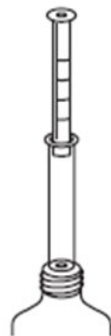


Figure 5



Figure 6

7. Empty the contents of the syringe directly into mouth by pushing the syringe plunger to the bottom of the syringe barrel (Figure 7). Or empty the syringe contents in a clean cup for diluting with water or fruit juices.
8. Rinse the syringe by drawing water into the syringe and pushing the syringe plunger to the bottom of the syringe barrel, at least three times (Figure 8).
9. Replace the cap on the bottle (leaving the bottle adaptor in place in the bottle neck) (Figure 9).

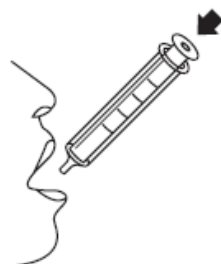


Figure 7



Figure 8

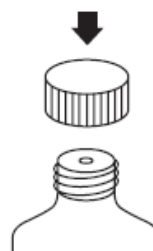


Figure 9

Levocarnitine Paediatric solution can be drunk directly or diluted further with water or fruit juices. If diluted, it should be drunk within 40 minutes of preparation.

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, this medicine 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 this medicine after the expiry date which is stated on the bottle label and carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

20 ml bottle: Discard after 30 days of first opening.

40 ml and 100 ml bottle: Discard after 60 days of first opening.

As stated in section 3 “*How to give your child Levocarnitine Paediatric*”, the paediatric solution can be drunk directly or diluted further with water or fruit juices. If diluted, it should be drunk within 40 minutes of preparation.

Do not throw away any medicines via wastewater or 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. Each ml of oral solution contains 300 mg of levocarnitine (30 % w/v).
- The other ingredients are sorbitol (E420), sodium methyl parahydroxybenzoate (E219), sucralose (E955), cherry flavour, sodium hydroxide (E524), tartaric acid (E334) and purified water (see section 2, “*Levocarnitine Paediatric contains sorbitol (E420), sodium methyl parahydroxybenzoate (E219) and sodium*”).

What Levocarnitine Paediatric looks like and contents of the pack

Levocarnitine Paediatric is a clear, colourless to yellowish solution with cherry odour packaged in white plastic bottle containing either 20 ml, 40 ml or 100 ml of oral solution closed with a plastic child resistant, tamper evident cap.

A 2 ml graduated oral syringe and a bottle adaptor are provided with the 20 ml pack size.

A 5 ml graduated oral syringe and a bottle adaptor are provided with the 40 ml or 100 ml pack sizes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Neon Healthcare Ltd.

8 The Chase, John Tate Road, Hertford, SG13 7NN, UK

Manufacturer

Conforma NV

Zenderstraat 10, Destelbergen, B-9070, Belgium

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