

PACKAGE LEAFLET: INFORMATION FOR THE USER

Carnitor 1 g Oral Solution (levocarnitine)

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 you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- 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 Carnitor 1 g Oral Solution is called Carnitor solution.

In this leaflet:

1. What Carnitor solution is and what it is used for
2. Before you take Carnitor solution
3. How to take Carnitor solution
4. Possible side effects
5. How to store Carnitor solution
6. Further information

1. What Carnitor solution is and what it is used for

Carnitor solution contains levocarnitine which is a type of protein. It is used to treat primary and secondary carnitine deficiency in adults and children over 12 years of age.

Carnitine deficiency occurs when the body has a shortage of levocarnitine. Carnitor solution makes up for your bodies lack of levocarnitine and helps give your body more energy.

2. Before you take Carnitor solution

Do not take Carnitor solution:

- if you are allergic to levocarnitine or any of the other ingredients in Carnitor solution. These ingredients are listed in section 6 of this leaflet.

If this applies to you, do not take Carnitor solution.

Tell your doctor before you take Carnitor solution if:

- you have severe kidney problems or kidney disease and are having dialysis
- you are diabetic and taking insulin, or any other drug to treat your diabetes
- you are taking anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting.

If any of the above applies to you, talk to your doctor or pharmacist.

Taking other medicines

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

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or if you become pregnant while taking Carnitor solution. Your doctor will decide whether or not you should continue to take your medicine. If you wish to breastfeed, ask your doctor for advice.

Driving and using machines

You can drive or use machines whilst taking Carnitor solution.

Important information about some of the ingredients in Carnitor solution

This product contains methyl hydroxybenzoate (E219) and propyl hydroxybenzoate (E217) which may cause immediate or delayed allergic reactions.

3. How to take Carnitor solution

Always take Carnitor solution exactly as your doctor has told you.

How much Carnitor solution should you take

Your doctor will carefully calculate the amount of Carnitor solution that you should take and may vary it depending on your response to the treatment. Your doctor may take blood and urine samples to check the amount of the drug in your body.

Method of administration

Carnitor 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 Carnitor solution is 200 mg per kg of your body weight per day. This should be taken over 2-4 doses. Higher doses of up to 400 mg per kg of your body weight per day may be necessary. Your doctor will tell you exactly how much to take and when to take it.

Maintenance therapy for haemodialysis patients

If significant benefit was gained by a first course of Carnitor injection, then ongoing therapy of 1 g per day of Carnitor solution may be taken. On the day of dialysis, Carnitor solution must be taken at the end of the session.

If you take more Carnitor solution than you should

If you take too much Carnitor solution, contact your doctor or immediately go to the nearest hospital casualty department.

If you forget to take Carnitor solution

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

If you stop taking Carnitor solution

Do not stop taking the medicine without first talking to your doctor.

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

4. Possible side effects

Like all medicines Carnitor solution can cause side effects, although not everybody gets them.

Side effects are:

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

Reporting of side effects

If you get 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 Carnitor solution

Keep out of the reach and sight of children.

Do not use Carnitor after the expiry date stated on the bottle. The expiry date refers to the last day of that month.

Store below 25°C and protect from light.

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

6. Further information

What Carnitor solution contains

- The active substance is levocarnitine. Each bottle contains 1 g of levocarnitine.
- The other ingredients are malic acid (E296), saccharin sodium (E954), sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217) and purified water.

What Carnitor solution looks like and contents of the pack

Carnitor solution is a clear colourless or light straw-coloured liquid. It comes in 10 ml amber glass bottles with fully removable plastic caps.

Marketing Authorisation Holder

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