

Carnitor® 1 g Oral Solution

(levocarnitine)

2970
25.05.22[11]

PATIENT INFORMATION LEAFLET

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 this medicine (listed in section 6).

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

Warnings and precautions

Talk to your doctor before taking 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.

Other medicines and Carnitor solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any 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.

Carnitor solution with food and drink

Not applicable.

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.

Carnitor solution contains sucrose, sorbitol, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217) and sodium

This medicine contains sucrose and sorbitol. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

This product contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) 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 TAKE CARNITOR SOLUTION

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

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 should 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 the forgotten dose. Simply continue with the next dose as planned.

If you stop taking Carnitor solution

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

If you have any further questions about the use of this medicine, 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 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 SOLUTION

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package to protect from light.
- Do not use Carnitor solution after the expiry date stated on the bottle. The expiry date refers to the last day of that month.
- If your medicines show any signs 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 your pharmacist. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Carnitor solution contains

The active substance is levocarnitine. Each 10 ml bottle contains 1 g of levocarnitine.

The other ingredients are sucrose, malic acid, sorbitol, saccharin sodium, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), mandarin flavour and purified water.

What Carnitor solution looks like and contents of the pack

Carnitor solution is a colourless or slightly yellow solution with an orange aroma.

It comes in 10 ml amber glass bottles with fully removable plastic caps.

Pack size – 10 bottles x 10 ml.

Manufacturer and product licence holder

Carnitor solution is manufactured by:
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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**Blind or partially sighted?
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leaflet in a format suitable for you.**

Levocarnitine 1 g Oral Solution

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In this leaflet Levocarnitine 1 g Oral Solution is called Levocarnitine solution.

In this leaflet:

1. What Levocarnitine solution is and what it is used for
2. Before you take Levocarnitine solution
3. How to take Levocarnitine solution
4. Possible side effects
5. How to store Levocarnitine solution
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1. WHAT LEVOCARNITINE SOLUTION IS AND WHAT IT IS USED FOR

Levocarnitine 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. Levocarnitine solution makes up for your bodies lack of levocarnitine and helps give your body more energy.

2. BEFORE YOU TAKE LEVOCARNITINE SOLUTION

Do not take Levocarnitine solution:

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

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

Warnings and precautions

Talk to your doctor before taking Levocarnitine 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.

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Other medicines and Levocarnitine solution

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Levocarnitine solution with food and drink

Not applicable.

Pregnancy and breast-feeding

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