

Carnitor® 1 g Solution for Injection

(levocarnitine)

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 you. Do not pass it on to others. It may harm them, even if their signs are the same as yours
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- In this leaflet Carnitor 1 g Solution for Injection will be called Carnitor injection.

What is in this leaflet:

1. What Carnitor injection is and what it is used for
2. What you need to know before you use Carnitor injection
3. How to use Carnitor injection
4. Possible side effects
5. How to store Carnitor injection
6. Contents of the pack and other information

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

Carnitor injection contains levocarnitine which is a type of protein. It is used to treat primary and secondary carnitine deficiency in adults, children, infants and newborn children. It can also be used to treat secondary carnitine deficiency in haemodialysis patients.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CARNITOR INJECTION

Do not take Carnitor injection:

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

Warnings and precautions

Talk to your doctor before using Carnitor injection 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 medicines, such as warfarin, or any other drug to reduce blood clotting.

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

Other medicines and Carnitor injection

Tell your doctor if you are taking any anticoagulant medicine, such as warfarin, or any other drug to reduce blood clotting. Tell your doctor if you are using, have recently used or might use any other medicines, including those obtained without a prescription.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Breast-feeding

Levocarnitine is a normal component of breast milk. If you wish to breast-feed, ask your doctor for advice.

Fertility

Levocarnitine has no safety issues on fertility.

Driving and using machines

You can drive or use machines whilst taking Carnitor injection.

3. HOW TO USE CARNITOR INJECTION

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

How much Carnitor injection will you be given

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

Method of administration

Your doctor will give the injection slowly into your vein (intravenous injection) over a period of 2-3 minutes.

Primary carnitine deficiency

The usual recommended dose is 100 mg per kg of your body weight per day. This will be given in 3-4 doses.

Secondary carnitine deficiency in haemodialysis patients (dialysis of the blood)

A dose of 20 mg per kg of your bodyweight should be given in the same way as above at the end of each dialysis session (assuming three sessions per week). The treatment should last at least three months, which is the time required to restore normal muscle levels of free carnitine. If significant benefit is seen following this first course of treatment ongoing therapy using 1 g per day of Carnitor Oral Solution may be used. On the day of dialysis Carnitor Oral Solution should be taken at the end of the dialysis session.

If you are elderly you do not need special precautions or modifications to Carnitor injection dosage.

If you use more Carnitor injection than you should

If you think you have been given too much Carnitor injection tell your doctor. If you have any further questions on using 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.

Common side effects (may affect up to 1 in 10 people):

- Mild stomach upsets such as stomach cramps and vomiting, diarrhoea, or you may feel or be sick for a short time.

Uncommon side effects (may affect up to 1 in 100 people):

- Drug-related body and/or skin odour (your doctor may reduce your dose to help lessen or stop the odour), headache, increased/high blood pressure or low blood pressure, altered taste, sudden and involuntary muscle contraction (muscle spasms), feeling abnormal, injection site reaction, fever.

Very rare side effects (may affect up to 1 in 10,000 people):

- International Normalised Ratio increased; for people also taking an anticoagulant medicine, such as warfarin, tests may show your blood is taking longer than usual to clot.

Not known side effects (frequency cannot be estimated from the available data):

- Convulsions*, itching, rash, muscle rigidity.

* In patients with prior convulsive episodes or underlying predisposing conditions to convulsions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 INJECTION

- Keep out of the reach and the sight of children.
- Do not use Carnitor injection after the expiry date stated on the sealed glass ampoule. The expiry date refers to the last day of that month.
- Do not above 25°C.
- Store in the original carton in order to protect from light.
- If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or in household waste. Return any medicine you no longer need to the pharmacist.

6. FURTHER INFORMATION

What Carnitor injection contains

- The active substance is levocarnitine inner salt.
- Each 5 ml ampoule contains 1 g levocarnitine. Also contains water for injection.

What Carnitor injection looks like and contents of the pack

Carnitor injection is a clear, colourless or light straw-coloured liquid. It comes in 5 ml amber glass ampoules. There are 5 ampoules in each pack.

Manufacturer and product licence holder

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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Levocarnitine 1 g Solution for Injection

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- In this leaflet Levocarnitine 1 g Solution for Injection will be called Levocarnitine injection.

What is in this leaflet:

1. What Levocarnitine injection is and what it is used for
2. What you need to know before you use Levocarnitine injection
3. How to use Levocarnitine injection
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1. WHAT LEVOCARNITINE INJECTION IS AND WHAT IT IS USED FOR

Levocarnitine injection contains levocarnitine which is a type of protein. It is used to treat primary and secondary carnitine deficiency in adults, children, infants and newborn children. It can also be used to treat secondary carnitine deficiency in haemodialysis patients.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LEVOCARNITINE INJECTION

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Warnings and precautions

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- you have severe kidney problems or kidney disease and are having dialysis
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How much Levocarnitine injection will you be given

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

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