

Package Leaflet: Information for the user

Carnitor® 1g Chewable Tablets

(levocarnitine)

APPROVED

By Asif Chohan at 9:20 am, May 17, 2021

MOCK UP

The name of your medicine is Carnitor 1g chewable tablets but will be referred to as Carnitor chewable tablets throughout the remainder of the 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 you only. Do not pass it on to others. It may harm them, even if their signs of illness 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. See section 4.

What is in this leaflet:

1. What Carnitor chewable tablets are and what they are used for
2. What you need to know before you take Carnitor chewable tablets
3. How to take Carnitor chewable tablets
4. Possible side effects
5. How to store Carnitor chewable tablets
6. Contents of the pack and other information

1. What Carnitor chewable tablets are and what they are used for

Carnitor chewable tablets contain levocarnitine which is a type of protein. They are 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 chewable tablets make up for your bodies lack of levocarnitine and help give your body more energy.

2. What you need to know before you take Carnitor chewable tablets

Do not take Carnitor chewable tablets:

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

Warning and precautions

Talk to your doctor or pharmacist before taking Carnitor chewable tablets 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 on a diet to reduce calorie intake
- you have an intolerance to some sugars
- you are taking anticoagulant medicines, such as warfarin, or any other drug to reduce blood clotting.

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

Other medicines and Carnitor chewable tablets

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 taking, have taken or might take 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 breastfeed, ask your doctor for advice if the benefit for you is greater than the potential risks for the baby.

Fertility

Levocarnitine has no safety issues on fertility.

Driving and using machines

You can drive or use machines whilst taking Carnitor chewable tablets.

Carnitor chewable tablets contain sucrose

If you have been told by the doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This product contains 1,8 g of sucrose per dose. This should be taken into account in patients with if you suffer of diabetes mellitus. May be harmful to the teeth.

3. How to take Carnitor chewable tablets

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

How many Carnitor chewable tablets should you take

Your doctor will carefully calculate the number of chewable tablets you should take and may change it depending on your response to treatment. Your doctor may take blood and urine samples to check the amount of the drug in your body.

Method of administration

Carnitor chewable tablets are for oral use. They should be chewed, not swallowed whole.

Primary and secondary Carnitine deficiency

The usual dose of Carnitor chewable tablets 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 many chewable tablets to take and when to take them.

Maintenance therapy for haemodialysis patients

If significant clinical benefit was gained by a first course of Carnitor injection, then ongoing therapy of one Carnitor chewable tablet per day may be taken. On the day of dialysis, the chewable tablet should be taken at the end of the session.

If you have serious kidney problems, treatment with Carnitor chewable tablets should not be prolonged and at high doses.

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

If you take more Carnitor chewable tablets than you should

An excessive dose of Carnitor chewable tablets can cause diarrhoea. If you take too many Carnitor chewable tablets, contact your doctor or immediately go to the nearest hospital casualty department.

If you forget to take Carnitor chewable tablets

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 chewable tablets

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

If you have any further questions on the use of 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, 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 on the skin, 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 the Yellow Card Scheme at: 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 chewable tablets

Keep out of the sight and reach of children

Do not use this medicine after the expiry date shown on the blisters or carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

If you have any unwanted tablets, don't dispose of them in your waste water or your household rubbish. Take them back to your pharmacist, who will dispose of them in a way that won't harm the environment.

If the product shows any signs of deterioration consult your pharmacist for advice.

6. Contents of the pack and other information

What Carnitor tablets contain

The active substance is Levocarnitine. Each chewable tablet contains 1g of levocarnitine.

The other ingredients are sucrose, magnesium stearate, mint flavor and liquorice flavour.

What Carnitor chewable tablets look like and contents of the pack

Carnitor chewable tablets are white, round chewable tablets. They come in blister packs containing 10 chewable tablets.

PL 20774/1874 Carnitor 1g chewable tablets

POM

Manufactured by: Afasigma S.p.A., Via Pontina km 30,400, 00071 Pomezia, Rome, Italy. Procured from within the EU.
Product Licence Holder: Quadrant Pharmaceuticals Ltd, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA.
Repackaged by: Maxearn Ltd, Unit 29, Oakhill Trading Estate, Devonshire Road, Worsley, Manchester, M28 3PT.

Leaflet prepared date 14th May 2021

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Is this leaflet hard to see or read?
Contact Quadrant
Pharmaceuticals Ltd,
Tel: 01204 471 269**

Package Leaflet: Information for the user Levocarnitine 1g Chewable Tablets

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What is in this leaflet:

1. What Levocarnitine chewable tablets are and what they are used for
2. What you need to know before you take Levocarnitine chewable tablets
3. How to take Levocarnitine chewable tablets
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1. What Levocarnitine chewable tablets are and what they are used for

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Levocarnitine deficiency occurs when the body has a shortage of levocarnitine. Levocarnitine chewable tablets make up for your bodies lack of levocarnitine and help give your body more energy.

2. What you need to know before you take Levocarnitine chewable tablets

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Leaflet prepared date 14th May 2021

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