

Package leaflet: Information for the user

Carnitor 1 g Chewable Tablets (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 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 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 Carnitor 1 g Chewable Tablets are called Carnitor chewable tablets.

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 body's 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.)

Warnings and Precautions

Tell your doctor 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 medicine, 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, have recently taken or might take any other medicine.

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.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or if you become pregnant while taking Carnitor chewable tablets. 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 chewable tablets.

Carnitor chewable tablets contain sugar

This product contains sugar. If you have been told by the doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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 take more Carnitor chewable tablets than you should

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 about 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.

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

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

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 chewable tablets

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 carton after Exp. The expiry date refers to the last day of that month.

Store below 25°C.

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 Carnitor chewable tablets contain

- The active substance is levocarnitine. Each 1 g chewable tablet contains 1 g of levocarnitine.
- The other ingredients are compressible sugar (DIPAC), magnesium stearate (E572), mint flavour and liquorice flavour.

What Carnitor chewable tablets look like

Carnitor chewable tablets are white, round pillow shaped chewable tablets, approximately 2.2 cm wide. They come in blisters containing two chewable tablets. The medicine comes in packs of 10, 30, 50 and 100 chewable tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Alfasigma S.p.A
Viale Sarca, n. 223
20126 Milan
Italy

Manufacturer

Sigma-tau Industrie Farmaceutiche Riunite S.p.A.
Pomezia, Italy.

This leaflet was last updated in May 2017