

Unofficial translation of the German package leaflet

Package leaflet: Information for the user

Biocarn[®] 1 g levocarnitine/3.3 ml syrup

Active substance: levocarnitine



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Biocarn[®] is and what it is used for
2. What you need to know before you take Biocarn[®]
3. How to take Biocarn[®]
4. Possible side effects
5. How to store Biocarn[®]
6. Contents of the pack and other information

1. WHAT BIOCARN[®] IS AND WHAT IT IS USED FOR

The active substance in Biocarn[®] is levocarnitine, a substance that occurs naturally in the body. Part of the levocarnitine required by the body is made by body itself in the liver and kidneys from the amino acids lysine and methionine, with the aid of adequate quantities of various B vitamins, vitamin C and the trace element iron. The rest is obtained directly from food.

Levocarnitine plays a key role in the transport of long-chain fatty acids into the mitochondria, the “powerhouses” of the cells. The levocarnitine concentration in the cells regulates whether fatty acids are burnt and converted into energy or whether they are stored in the cells as triglycerides (neutral fats). In addition, levocarnitine removes the waste products of energy metabolism from the mitochondria, thus providing performance-stabilising cell protection. The high therapeutic effect of levocarnitine is due to better energy supply to skeletal muscle and cardiac muscle.

Biocarn[®] is used:

- As substitution therapy for primary and secondary systemic carnitine deficiency.
- As an attempted treatment of special forms of muscular dystrophy (muscle wasting) and lipid accumulation (build-up of fats) associated with primary muscle carnitine deficiency.
- To complement the treatment of progressive Duchenne muscular dystrophy, if functioning skeletal muscle is still present.
- To replace dialysis-induced levocarnitine depletion in patients on long-term dialysis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BIOCARN[®]

Do not take Biocarn[®]:

If you are allergic to levocarnitine, methyl 4-hydroxybenzoate, propyl 4-hydroxybenzoate, or one of the other ingredients of this medicine listed in section 6.

Warnings and precautions

Talk to your doctor or pharmacist before taking Biocarn[®].

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before you start taking this medicine.

Other medicines and Biocarn[®]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular:

- Pivalate, which increases the elimination of levocarnitine via the kidneys.
- Valproate, emetine or zidovudine, which can themselves cause levocarnitine deficiency.

Biocarn[®] with food, drink and alcohol

No interactions with food and drink are currently known.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

No specific precautions are necessary.

Important information about some of the ingredients of Biocarn[®]

Biocarn[®] contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Biocarn[®].

Biocarn[®] is suitable for diabetics. One measuring cup (3.3 ml) is equivalent to 0.056 carbohydrate units.

3. HOW TO TAKE BIOCARN[®]

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

The recommended dose is 1 g levocarnitine (3.3 ml Biocarn[®] = 1 measuring cup) per day. On dialysis days, Biocarn[®] is to be taken after completion of the dialysis.

Duration of treatment

The duration of treatment is to be decided by the doctor.

Treatment of dialysis-induced levocarnitine depletion is a long-term therapy.

Biocarn[®] can be taken diluted with liquid. It can be taken with or without food, and also with hot drinks and juices.

If you take more Biocarn[®] than you should

Biocarn[®] contains sorbitol and may therefore have a laxative effect in the event of overdose. Treatment measures are not usually required; please consult a doctor if necessary. Levocarnitine is not known to have any toxic (poisonous) effects.

If you forget to take Biocarn[®]

Do not take a double dose to make up for a forgotten dose, but instead continue taking the medicine as normal.

If you stop taking Biocarn[®]

The success of the treatment will be put at risk if you stop taking Biocarn[®].

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Biocarn[®] can cause side effects, although not everybody gets them.

The classification of side effects is based on the following frequencies:

Very common	more than 1 in 10 patients treated
Common	fewer than 1 in 10 but more than 1 in 100 patients treated
Uncommon	fewer than 1 in 100 but more than 1 in 1,000 patients treated
Rare	fewer than 1 in 1,000 but more than 1 in 10,000 patients treated
Very rare	fewer than 1 in 10,000 patients treated, and isolated cases
Unknown	frequency cannot be estimated from the available data

Possible side effects

Uncommon (fewer than 1 in 100 but more than 1 in 1,000 patients treated)

Nausea and vomiting may occasionally occur when taking the usual therapeutic doses of between 1 and 3 g levocarnitine.

Very rare (fewer than 1 in 10,000 patients treated, and isolated cases)

In very rare cases, seizures have occurred following the oral or intravenous administration of levocarnitine. An increase in frequency and intensity of seizures has been reported in predisposed patients.

In very rare cases, a fish-like body odour may develop after long-term use and high doses.

Other possible side effects

Methyl 4-hydroxybenzoate and propyl 4-hydroxybenzoate can cause hypersensitivity reactions, including delayed reactions.

Please tell your doctor or pharmacist if you are severely affected by one of the listed side effects, or if you notice side effects that are not listed in this package insert.

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 to the Bundesinstitut für Arzneimittel und Medizinprodukte [German Federal Office for Drugs and Medical Devices (BfArM)], Abt. Pharmakovigilanz [Pharmacovigilance Department], Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, website: <http://www.bfarm.de>. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BIOCARN®

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 label and the carton after "Expiry date". The expiry date refers to the last day of that month.

Note about shelf-life after opening

After first opening, the bottle must be closed tightly and stored at room temperature. Do not use Biocarn® for longer than 3 months.

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 Biocarn® contains

The active substance is: levocarnitine

3.3 ml Biocarn® (= 1 measuring cup) contains 1 g levocarnitine, corresponding to 303 mg of levocarnitine per ml syrup.

The other ingredients are:

Purified water, sorbitol solution 70% (non crystallizing), lemon flavour, methyl 4-hydroxybenzoate, propyl 4-hydroxybenzoate, hydrochloric acid 36% (for pH adjustment)

What Biocarn® looks like and contents of the pack

Biocarn® is clear and colourless. The syrup is presented in 50 ml brown glass bottles with dropper, measuring cup and screw closure.

Biocarn® is available as original packs of 1 x 50 ml syrup and as multi-packs with 3 x 50 ml syrup.

Pharmaceutical company and manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG
Kuhloweg 37
58638 Iserlohn

This leaflet was last revised in September 2014.