

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

# **CARNITINE SOLUTION 30%**

## **Oral Solution**

### **Composition**

Each 1 ml contains:

L-carnitine 300 mg (30%)

For information about inactive and allergenic ingredients, see section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Further Information”.

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Carnitine Solution 30% is intended for the treatment of carnitine deficiencies.

The solution is intended for oral use only, and not for injection.

### **Therapeutic group**

Amino acids and derivatives.

Carnitine is found naturally in the cells of the human body, and plays a fundamental role in producing and transporting energy.

### **2. BEFORE USING THE MEDICINE**

#### **Do not use the medicine if:**

you are sensitive (allergic) to the active ingredient L-carnitine or any of the additional ingredients contained in the medicine.

### **Special warnings regarding use of the medicine**

**Before treatment with Carnitine Solution 30%, tell the doctor:**

- If you have diabetes and are being treated with insulin or oral antidiabetic medicines to reduce blood sugar levels. Using this medicine causes a further reduction in blood sugar levels. In this case, you will have to perform frequent blood tests, and the doctor may change the dosage of insulin or of oral antidiabetic medicines.

- If you have a predisposition to seizures. Treatment with this medicine may cause seizure episodes. If you already suffer from convulsive attacks, this medicine may increase their number and intensity.
- If you suffer from kidney problems (severe renal insufficiency or terminal renal insufficiency) or if you are in dialysis. In these cases, the doctor will monitor your kidney functions during the treatment with the medicine, especially if treatment is prolonged (see section “How should you use the medicine”).
- If you are using medicines against hypercoagulation. In this case, you will have to perform regular tests for hypercoagulation.

No tolerance (reduction in drug efficacy with prolonged use) to the medicine or dependence on the medicine has been observed.

If you are sensitive to any type of food or medicine, inform the doctor before taking the medicine.

While under treatment and especially at the beginning, you must be under the doctor’s supervision in order to check your response to the medicine.

### **Drug interactions**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially if you are taking:

Anticoagulant medicines, because in rare cases, taking Carnitine Solution 30% at the same time as these medicines may cause changes in coagulation. In these cases, coagulation tests will be required on a regular basis (see section “Special warnings regarding use of the medicine”).

Medicines for epilepsy (valproic acid), antibiotics (containing pivalic acid, cephalosporin), or medicines for cancer (cisplatin, carboplatin or ifosfamide), because they may reduce the level of Carnitine Solution 30% in the blood.

### **Pregnancy, breastfeeding and fertility**

#### Pregnancy

The medicine can be used during pregnancy if your doctor thinks that the benefit of taking the medicine is greater than the risk for the unborn child.

#### Breastfeeding

L-carnitine is one of the components of breast milk. The medicine can be used during breastfeeding if the doctor thinks that the benefit for you is greater than the potential risk for the baby.

#### Fertility

The medicine has no negative effect on fertility.

### **Driving and using machines**

The medicine has no effect on driving or using machines.

### **Important information about some of the ingredients of the medicine**

Each 1 ml contains: 0.028 grams of sucrose and 0.07 grams of sorbitol. If you have intolerance to sucrose or other sugars, inform the doctor before taking the medicine.

Carnitine Solution 30% contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause an allergic reaction.

Sodium content in 1 ml of solution: 0.1875 mg. This medicine contains less than 23 mg of sodium per treatment dose, and is therefore considered to be sodium-free.

Each ml contains: 5.2 mg of alcohol (ethanol). The amount in each ml of medicine is equal to 0.13 ml of beer or 0.05 ml of wine. The small amount of alcohol in this medicine has no significant effect.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparation.

The dosage varies according to the age and weight of the patient.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

In adults and adolescents aged 12 years and over:

1 to 3 grams per day divided into 2 or 3 doses for a patient weighing 50 kilograms. High doses must be used very carefully in consultation with the doctor. Start with a dosage of 1 gram per day, and increase slowly, while being assessed by the doctor.

Use in children:

50 to 100 mg per kg per day. High doses must be used carefully in consultation with a doctor. Start with a dosage of 50 mg per kg per day, and increase gradually to a maximum of 3 grams per day, while being assessed by the doctor.

Carnitine deficiencies secondary to hemodialysis:

The recommended dose is 2-4 grams per day.

If you have a severe kidney problem, the oral solution should not be taken for a prolonged period and should not be taken at a high dosage.

There are no special precautions or modifications to the dosage of the medicine in the elderly.

If you have diabetes and are being treated with insulin or with an oral medicine that lowers sugar levels, your doctor will ask you to perform frequent blood tests, as Carnitine Solution 30% could cause an additional decrease in sugar levels. The doctor will adjust the dosage of insulin or of the oral medicine to reduce blood sugar (see section "Special warnings regarding use of the medicine").

**Do not exceed the recommended dose.**

**If you accidentally take a higher dosage**

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by the doctor!

A possible side effect of overdose is diarrhea.

**If you forgot to take the medicine** at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment as recommended by the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

#### **Method of administration**

Take the medicine with or after a meal.

The solution can be taken undiluted, or diluted in a beverage or liquid food.

Drink the solution slowly. Diluting the solution and drinking slowly may reduce side effects.

#### **4. SIDE EFFECTS**

As with any medicine, use of Carnitine Solution 30% may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

##### **Common side effects (may affect 1 user in 10):**

- Vomiting
- Nausea
- Diarrhea
- Abdominal cramps

##### **Uncommon side effects (may affect 1 user in 100):**

- Headaches
- Increased blood pressure or high blood pressure
- Low blood pressure
- Altered sense of taste
- Digestive problems
- Dry mouth
- Foul odor of urine, sweat and mouth \*
- Sudden involuntary muscle spasms
- Chest pain
- Feeling abnormal
- Fever

##### **Very rare side effects (may affect up to 1 user in 10,000)**

- Changes in blood coagulation \*\*

##### **Side effects of unknown frequency (effects whose frequency has not been determined):**

- Seizures \*\*\*
- Dizziness
- Irregular heartbeat (palpitations)
- Breathing difficulties
- Itch

- Skin rash
  - Myasthenia – an illness characterized by muscle weakness \*\*\*\*
  - Muscle tension
- \* Occurs in patients with severe kidney problems or patients in dialysis, as a result of the build-up of L-carnitine metabolites in the blood.
- \*\* Occurs in patients concomitantly using medicines against blood coagulation.
- \*\*\* Seizure episodes in patients who have or have not suffered in the past from seizures.
- \*\*\*\* Occurs in patients with terminal renal insufficiency.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

#### Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

#### **5. HOW SHOULD THE MEDICINE BE STORED?**

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.

#### **Storage conditions**

**Store this medicine in a cool place. Do not freeze.**

**After first opening, the medicine may be used for 15 days.**

Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

#### **6. FURTHER INFORMATION**

**In addition to the active ingredient, the medicine also contains:**

Sorbitol 70% solution, sucrose, sodium methyl p-hydroxybenzoate, sodium propyl p-hydroxybenzoate, colorless cherry flavor (contains ethanol), colorless sour black cherry flavor (contains ethanol), tartaric acid (for pH adjustment), purified water.

**What the medicine looks like and the contents of the package:**

Carnitine Solution 30% is a clear liquid, colorless to slightly yellow.

Each bottle contains 20 ml solution.

**Name of License Holder and its Address:**

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020

**Name of Manufacturer and its Address:**

Alfasigma S.p.A., Bologna, Italy

**This leaflet was revised in November 2023 according to MOH guidelines.  
Registration number of the medicine in the National Drug Registry of the  
Ministry of Health:**

Carnitine Solution 30%: 119.07.23815

CARN 30% ORA SOL PL SH 271123

The logo for Teva, consisting of the word "teva" in a bold, lowercase, sans-serif font. The letter 'v' is stylized with a diagonal slash through it.