ÆSCULAPIUS
FARMACEUTICI

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

LEVOCARVIT "1g/10 ml ORAL SOLUTION"

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1g/10 ml oral solution
Each 10 ml monodose vial contains:
Active substance: L(-)carnitine g 1

For excipients see 6.1.

3. PHARMACEUTICAL FORM

Oral solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Primary and secondary deficiencies of carnitine.

4.2 Posology and method of administration

Meanly 2-3 g per day.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and special precautions for use

L(-)carnitine does not have any risk of tolerance or addiction due to the fact it is a natural product.

4.5 Interactions with other medicinal product and other forms of interaction

No interactions nor incompatibilities with other medicinal are known.

4.6 Pregnancy and lactation

There are no contraindications to the LEVOCARVIT use of the product during pregnancy or lactation.

4.7 Effects on the ability to drive and use machines

LEVOCARVIT has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Light gastro-intestinal disturbances have been reported and, in uremic patients, light symptoms of miasthenia.
Convulsion cases have also been reported in patients, with or without previous convulsive activity, that received "Levocarnitine" orally or intravenously.

4.9 Overdose

No cases of overdosage have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Aminoacids and derivatives, ATC code: A16AA01.
L(-)carnitine is a natural substance that is present in all the cells where it plays a fundamental role in the utilization of lipidic substrates. In fact it is the only carrier that can be used by the long chain fat acids to cross the mitocondrial internal membrane and to be directed to ß-oxidization. The main natural reserve of carnitine are the skeleton muscles and the myocardium that preferentially, for energetic purposes, uses the fat acids. It has also been noted that uremic patients, subjected to periodic haemodyalisis, show low muscle levels of L(-)carnitine together with the great loss of this substance with the dyalisis liquid. For this reason the administration of carnitine in these patients is right to reestablish the normal levels of the substance.

5.2 Pharmacokinetic properties

L(-)carnitine, administered orally, is absorbed at intestinal level and reaches the maximum haematic levels at the 3rd hour. Good levels are maintained for about 9 hours. It is excreted by kidneys under not modified form for over the 80% within 24 hours.

5.3 Preclinical safety data

The preclinical data show absence of any risk for the humans on the base of conventional studies of safety pharmacology, toxicity after repeated administration, genotoxicity, cancerogenic potential, reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, 70% sorbitol solution, Methyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, cherry and sour black cherry aromas, purified water.

- **Addictional notes:**

- The product contains 5,60 g of sucrose. If taken according to the recommended dosage, each dose gives until 0,560 g of sucrose.
  The product is contra-indicated in the hereditary intolerance to the fructose, in the malabsorbance syndrome of the glucose-galattose or in the deficiency of sucrose-isomaltase.
- The product contains 14 g of sorbitol. If taken according to the recommended dosage, each dose gives until 1,4 g of sorbitol.
  Patients with rare hereditary problems of fructose intolerance should not take this medicinal.
- It can give allergic reactions, also delayed.

6.2 Incompatibilities

Not pertinent.

6.3 Shelf-life

4 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Monodose vials containing a clear, colourless solution with a fruit aroma and a pleasant and sweet taste.
1g/10ml oral solution – 10 monodose containers of 10 ml

6.6 Instructions for use

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

AESCULAPIUS FARMACEUTICI S.r.l. – Via Cefalonia, 70 – 25124 Brescia ITALY

8. MARKETING AUTHORISATION NUMBER

MA No. 025943010

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Renewal date: June 2010

10. DATE OF REVISION OF THE TEXT

March 2017