METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

009672-TDS-ENG-2025

LEVOCARNITINA (EUR. PH.)		
DESCRIPTION DCI: levocarnitine	DESCRIPTION DOE: LEVOCARNITINA	
CAS Nº: 541-15-1	EC Nº: 208-768-0	AEMPS CODE: 8694A
MOL. WEIGHT: 161,2	MOL. FORMULA: C7H15NO3	ARTICLE CODE: 009672

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals, hygroscopic
Solubility	Freely soluble in water, soluble in warm ethanol (96 %), practically insoluble in acetone
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
pH	6.5 - 8.5
Specific optical rotation	-29.0 / -32.0
Related substances	
Impurity A	=< 0.3 %
Unspecified impurities	=< 0.10 %
Total (excluding impurity A)	=< 0.5 %
Chlorides	=< 200 ppm
Sulfates	=< 300 ppm
Water	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed. Store in a cool, dry place, protected from moisture.

REMARKS

Levocarnitine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses
L-carnitine is an amino acid derivative that acts as an essential cofactor in the metabolism of fatty acids in the heart, liver, and skeletal muscle. It is usually synthesized in the liver, brain, and kidneys. In plasma and tissues it is found in free form and as acetylcarnitine esters. It is used in the treatment of primary carnitine deficiency, and in those situations that cause secondary loss of carnitine, especially in organic acidurias, beta-oxidation disorders, hemodialysis treatment, or ischemic heart disease. A carnitine supplement may also be beneficial in myopathies and cardiomyopathies. It is also used in

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carnitine deficiency caused by prolonged treatments with valproic acid, pivampicillin, adriamycin and tricyclic antidepressants. Another use is as a nutritional supplement in premature children, since it allows a better use of fats and a gain in weight is obtained. The use of the L form is preferred, since it is believed that only the L form has therapeutic activity of the two isomers. In addition, supplementation with DL-carnitine can lead to a carnitine deficiency.

Dosage
Very variable. From 100-300 mg / day of L-carnitine orally as anabolic and orexygen, up to 1-3 g / day as a nutritional supplement.

Side effects
Gastrointestinal complaints have been reported such as nausea, vomiting, diarrhea, and cramping. Some patients have presented alterations of body odor. In chronic hemodialysis patients myasthenia may appear in the case of administration of the racemic form (DL).

Precautions
It is not recommended to administer high doses of levocarnitine orally for long periods of time to patients with severe renal dysfunction, due to the accumulation of trimethylamine and trimethylamine N-oxide metabolites.