

DATASHEET

1 TRADE NAME OF THE MEDICINAL PRODUCT

VAMINOLACT

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml contains:

<u>Active ingredients</u>	<u>Quantity</u>
Alanine	6.3 g
Arginine	4.1 g
Aspartic acid	4.1 g
Cysteine (+ L-Cystine)	1.0 g
Glutamic acid	7.1 g
Glycine (Aminoacetic acid)	2.1 g
Histidine	2.1 g
Isoleucine	3.1 g
Leucine	7.0 g
Lysine monohydrate corresponding to Lysine	5.6g
Methionine	1.3 g
Phenylalanine	2.7 g
Proline	5.6 g
Serine	3.8 g
Taurine	300 mg
Threonine	3.6 g
Tryptophan	1.4 g
Tyrosine	500 mg
Valine	3.6 g

Total amount of amino acids: 65.3 g/l of which 31.9 g, including cysteine, histidine and tyrosine, are essential.

pH: 5.2

Osmolality: 510 mOsm per kg water

Nitrogen content: 9.3 g/l.

Electrolytes: None

Energy content: 1.0 MJ/l (240 kcal/l)

Antioxidant additives: None

3 PHARMACEUTICAL FORM

Amino acid solution for intravenous nutrition

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

VAMINOLACT is indicated as a source of amino acids in children needing intravenous nutrition.

4.2 Posology and method of administration

Recommended dosage:

Newborns: Up to 35 ml per kg body weight per 24 h, the full dosage being reached by gradual increases during first week of administration.

Children	<u>Body weight kg</u>	<u>Dosage ml/kg/24 h</u>
	10	24
	20	18.5
	30	16
	40	14.5

The duration of infusion should be at least 8 hours.

VAMINOLACT may be infused into the same central or peripheral vein as glucose and/or fat emulsion.

4.3 Contra-indications

VAMINOLACT is contraindicated in patients with inborn errors of amino acid metabolism, severe liver dysfunction and in severe uraemia when dialysis facilities are not available.

4.4 Special warnings and special precautions for use

Intravenous infusion of amino acids is accompanied by increased urinary excretion of the trace elements copper and, in particular zinc, which should be taken into account in the dosing of trace elements, particularly during long-term intravenous nutrition.

4.5 Interaction with other medicaments and other forms of interaction

Not to be expected.

4.6 Pregnancy and lactation

Not applicable

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Nausea occurs rarely. Transient increases in liver functions tests during intravenous nutrition have been reported. The reasons are at present unclear. The underlying disease, the components and their amounts in the intravenous feeding regimens have been suggested.

Hypersensitivity reactions have been reported with amino acid solutions.

As with all hypertonic infusion solutions, thrombophlebitis may occur when peripheral veins are used. The incidence may be reduced by the simultaneous infusion of Intralipid.

4.9 Overdose

Vomiting, flushing and sweating have been observed if VAMINOLACT is administered at a higher rate than recommended.

In case of symptoms due to overdose, the infusion should be slowed down or discontinued.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The amino acid composition of VAMINOLACT is based on that of human milk. Apart from their nutritive properties, the amino acids should have no specific pharmacodynamic effects when administered at recommended rates.

To optimize the utilization of supplied amino acids, adequate energy should be supplied in the form of carbohydrates (preferable glucose) and fat.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of the infused amino acids are essentially the same as for amino acids supplied by ordinary food. However, the amino acids of dietary protein first enter the portal vein and then the systemic circulation, while intravenously infused amino acids reach the systemic circulation directly.

5.3 Preclinical safety data

Preclinical safety studies with VAMINOLACT demonstrated good tolerance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<u>Other ingredients</u>	<u>Quantity</u>
Water for injections	to 1000 ml

6.2 Incompatibilities

VAMINOLACT can only be mixed with other medicinal products for which compatibility has been documented. See 6.6 Instructions for use/handling.

6.3 Shelf-life

24 months

6.4 Special precautions for storage

Store below 25°C.
Do not freeze.

6.5 Nature and contents of container

Light- weight glass bottles 100 ml and 500 ml.

6.6 Instructions for use/handling

COMPATIBILITY

Additives

Only medicinal, nutritional or electrolyte solutions for which compatibility has been documented may be added to VAMINOLACT. Additions should be made aseptically.

The following can be added to 500 ml VAMINOLACT, separately or together:
Up to 200 mmol Na⁺, 160 mmol KCl, 35 mmol Ca gluconate and 15 mmol Mg SO₄.
Up to 30 ml Peditrace can be added to 500 ml VAMINOLACT.

The simultaneous administration of VAMINOLACT and Intralipid, for example via an infusion canula with a three-way tap, will reduce the osmolality of the solution which reaches the vein. This has the effect of reducing the risk of thrombophlebitis when infusing into a peripheral vein.

STABILITY

Additives

When additions are made to an infusion solution, the infusion should be completed within 24 hours to prevent microbiological contamination. When 30ml Peditrace alone is added to 500 ml VAMINOLACT, the mixture is stable for up to 12 hours. The leftover contents of opened bottles should be discarded and not saved for later use.

MEDICINE CLASSIFICATION

General Sale Medicine

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DATE OF PREPARATION
31st March, 2010