Vaminolact™

Description
Amino acid solution for intravenous nutrition.

Vaminolact™ is an electrolyte-free, clear, colourless to slightly yellow solution of amino acids, for intravenous nutrition in infants and children.

Composition
Amino acids (g/l):

Alanine	6.3
Arginine	4.1
Aspartic acid	4.1
Cysteine/cystine	1.0
Glutamic acid	7.1
Glycine (amino acetic acid)	2.1
Histidine	2.1
Isoleucine	3.1
Leucine	7.0
Lysine	5.6
Methionine	1.3
Phenylalanine	2.7
Proline	5.6
Serine	3.8
Taurine	0.3
Threonine	3.6
Tryptophan	1.4
Tyrosine	0.5
Valine	3.6

Water for injections to 1000 ml.

Total amount of amino acids: 65.3 g/l of which 31.9 g, including cysteine, tyrosine and histidine, are essential.
Nitrogen content: 9.3 g/l
Electrolytes: None
Antioxidant additives: none
Energy content: 1.0 MJ (240 kcal)
pH: 5.2
Osmolality: 510 mosmol per kg water

Clinical pharmacology
The amino acid composition of Vaminolact is based on that of human milk. Vaminolact contains the 18 essential and non-essential amino acids needed for synthesis of body proteins. Furthermore, it contains taurine, an aminosulfonic acid which is also present in human milk.

The intracellular concentration of taurine is normally high, particularly in the mature retina, in muscle and in developing brain tissue. In children, long term intravenous nutrition without taurine has induced low taurine levels and altered electro-retinograms
which normalised after taurine supplementation.

Vaminolact has been shown to result in positive nitrogen balance in preterm and terms of infants. Vaminolact does not contain carbohydrates and is electrolyte-free to allow individually adjusted administration.

To ensure maximal utilisation of the infused amino acids for protein synthesis, the patient's requirements of energy (given as carbohydrates and fat), vitamins and trace elements should be met.
Glucose is recommended as the source of carbohydrates.

Indications
Vaminolact is indicated as a source of amino acids for protein synthesis and of taurine in infants and children requiring intravenous nutrition.

Contraindications
Vaminolact is contra-indicated in patients with inborn errors of amino acid metabolism, irreversible liver damage and in severe uremia when dialysis facilities are not available.

Caution
Intravenous infusion of amino acids may be 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

Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. When used in neonates and children below 2 years, Vaminolact should be protected from ambient light until administration is completed

Adverse events
Nausea occurs rarely. Transient increase in liver tests during intravenous nutrition has been reported. The reasons are at present unclear. The underlying disease and the intravenous feeding regimens (components and their amounts) have been suggested.
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®.

Dosage and administration
Recommended dosage

	Body weight kg	Dosage ml/kg/day
Infants		up to 35*
Children	10	24**
	20	18.5**
	30	16**
	40	14.5**

* The dosage should be gradually increased to this value during the first week of life and the infusion should preferably be given continuously over 24 hours.

** The duration of infusion should be at least 8 hours.

Administration
Vaminolact may be infused into the same central of peripheral vein as glucose and fat emulsion by means of a Y-connector near the infusion site.
Discard any unused contents.

Compatibility

The following can be added to 500 ml Vaminolact, separately or together, without risk of precipitation: Up to 200 mmol sodium, 160mmol potassium as chloride, 35 mmol calcium as glubionate and 15 mmol magnesium as sulphate and up to 30 ml Ped-el N (Peditrace). Additions should be performed aseptically immediately before the start of the infusion.

Shelflife and Storage

Storage instructions and expiry date are stated on the label.
When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed.

Packsizes

Bottles of 100 ml and 500 ml.

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Manufactured by
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for Fresenius Kabi AB, Uppsala, Sweden

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