Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vaminolact solution for infusion, 500 ml bottle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

in each 1000 ml

For a full list of excipients, see section 6.1.

Product Properties
Amino acids 65.3 g/l
Total Nitrogen 9.3 g/l corresponding to 58 g/l protein
Energy 240 kcal (1.0MJ)/l
Osmolality 510 mosmol/kg water
pH 5.2

3 PHARMACEUTICAL FORM

Solution for infusion
A clear, colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Clinical conditions in paediatric patients when enteral supply of protein is insufficient, undesirable or impossible.

4.2 Posology and method of administration

Neonates, infant, children and adolescents:

Age groups (age range)	**Dosage range**	
	mL/kg bw/d	**g AA/kg bw/d**
Neonates (birth to <1 month of age)		

Preterm Neonates		
1st Day	23 to 38 mL/kg/d	1.5 to 2.5 g AA/kg/d
≥2nd Day	38 to 54 mL/kg/d	2.5 to 3.5 g AA/kg/d
Gradual dose increase during the first days of infusion should be used, starting with a dose such as 23 to 38 mL/kg/d (corresponding to 1.5 to 2.5 g amino acids/kg/d) on the first day and increasing to 38 to 54 (corresponding to 2.5 to 3.5 g amino acids/kg/d) on the second day onwards.		
Term Neonates	23 to 46 mL/kg/d	1.5 to 3.0 g AA/kg/d
Gradual dose increase to the target dose should be used during the first days of infusion.		
Infants (≥1 month to <2 years of age)	15 to 38 mL/kg/d	1.0 to 2.5 g AA/kg/d
Children (≥2 years to <12 years of age)	15 to 31 mL/kg/d	1.0 to 2.0 g AA/kg/d
Adolescents (≥12 years to <17 years of age)	15 to 31 mL/kg/d	1.0 to 2.0 g AA/kg/d
AA = amino acids; bw = body weight		

The duration of infusion should be at least 8 hours, preferably 12 hours as cyclic infusion or 24 hours as continuous infusion. In neonates and infants, the recommended duration of continuous infusion is 24 hours/d.

Method of administration
For intravenous use only.
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 (see section 4.4, 6.3 and 6.6).

4.3 Contraindications

Vaminolact is contraindicated in patients with irreversible liver damage and in severe uraemia where dialysis facilities are not available.

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

In extremely sick, premature and small babies requiring neonatal intensive care, liver function is likely to be immature and/or disturbed. Amino acids which, to a large extent, are metabolised by the liver may therefore accumulate in plasma. In this clinical condition, monitoring of amino acid concentration during therapy is advisable.

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 (see sections 4.2, 6.3 and 6.6).

Care must be taken when infusing large volume of fluids to patients with cardiac insufficiency. Amino acids must also be infused with caution in patients with disturbed protein metabolism. If the product is given together with electrolytes, electrolyte disturbance as e.g. hyperkalaemia, hypernatraemia should be corrected prior to the intravenous infusion. As with any form of nutrition, disturbances in acid-base homeostasis i.e., acidosis and alkalosis need to be corrected. Serum electrolytes, blood glucose levels, acid base balance and volume status should be monitored regularly.

As with all central venous infusions, complications of catheter insertion include air embolism and central venous thrombosis.

4.5 Interaction with other medicinal products and other forms of interaction

Amino acid solutions may precipitate acute folate deficiency and folic acid should be given daily.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of Vaminolact in pregnant women.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Nausea may occur rarely. Thrombophlebitis may occur when peripheral veins are used, but the incidence is reduced by the simultaneous infusion of a fat emulsion.

Transiently increased liver enzymes possibly occurring during intravenous infusion return to normal levels upon stopping artificial feeding. Cholestasis reflected by increased bilirubin levels reported in some patients during artificial nutrition is not specifically attributed to the product itself.

Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the HPRA, Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2 or by email to: medsafety@hpra.ie

4.9 Overdose

Infusion rates and volumes should be carefully monitored in infants.
Excessive infusion rates may result in nausea, vomiting, flushing and sweating. The effects of overdosage are likely to be due to the volume infused and the hypertonicity of the solution, i.e. circulatory overload.

The amount required to produce this effect will vary depending on the patient's age, weight and general condition. There are no specific antidotes for overdosage.

In case of suspected overdose the infusion should be stopped. If clinically required, supportive measures are indicated. With close biochemical monitoring specific abnormalities need to be treated appropriately, possibly including amongst others the careful infusion of vasopressors, hypotonic solutions and diuretics, sodium bicarbonate in case of metabolic acidosis.

Any corrective therapeutic intervention may be associated with side effects which need to be treated according to medical practice.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vaminolact is formulated to supply amino acids based on the protein profile of human breast milk. It includes taurine (2 aminoethane), a sulphonic amino acid and an end product of methionine and cysteine metabolism.

It has been demonstrated that taurine plays an important role in growth, development of the brain and maturation of retinal function and is also involved in hepatic biliary conjugation, especially in the neonate where bile acids are conjugated almost exclusively with taurine until some time after birth.

5.2 Pharmacokinetic properties

The distribution and metabolism of intravenously infused amino acids is well known and is similar to that of dietary protein. However, there are differences, one of which is that when dietary protein is metabolised, the liver is exposed to high concentrations of amino acids as the protein enters the systemic system via the portal vein and the liver.

With slow infusion of Vaminolact the amino acids enter the systemic circulation directly and hence the excessive elevation of plasma amino acids and urinary loss is avoided. Taurine is metabolised mainly by urinary excretion and by conjugation with bile acids.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Additions to Vaminolact should only be made where compatibility is known.

6.3 Shelf life

2 years

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 (see section 4.2, 4.4 and 6.6).

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

Light weight glass bottle (Ph. Eur. Type II) sealed with a butyl rubber stopper.

Pack sizes: - 12 x 500ml
- 10 x 500ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Single use only, discard any unused portion.
Do not use if solution is cloudy or if visible particles are present.
Any unused medicinal product or waste material should be disposed of in accordance with the local requirements.

When used in neonates and children below 2 years, protect from light exposure, until administration is completed. Exposure of Vaminolact to ambient light, especially after admixture with trace elements and/ or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure (see section 4.2, 4.4 and 6.3).

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

PA2059/065/002

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April 2023