SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vaminolact solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amino acids	Amount
Alanine Ph Eur	6.3 grams
Arginine Ph Eur	4.1 grams
Aspartic acid Ph Eur	4.1 grams
Cysteine/Cystine	1.0 grams
Glutamic acid Ph Eur	7.1 grams
Glycine BP	2.1 grams
Histidine USP	2.1 grams
Isoleucine Ph Eur	3.1 grams
Leucine Ph Eur	7.0 grams
Lysine	5.6 grams
Methionine Ph Eur	1.3 grams
Phenylalanine Ph Eur	2.7 grams
Proline Ph Eur	5.6 grams
Serine Ph Eur	3.8 grams
Taurine	0.3 grams
Threonine USP	3.6 grams
Tryptophan USP	1.4 grams
Tyrosine USP	0.5 grams
Valine Ph Eur	3.6 grams

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
Acetate	Nil
Energy	240 kcal (1.0 MJ)/l
Osmolality	510 mosmol/kg water
pH	5.2

Free from antioxidant additives, chlorides and other inorganic electrolytes.

3. PHARMACEUTICAL FORM

Solution for infusion
A clear and 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).

To achieve optimum utilisation of administered amino acids, adequate energy sources, e.g. glucose and lipid emulsion (Intralipid®) should be provided together with electrolytes, trace elements (Peditrace® or Additrace®) and vitamins (Solivito® N, Vitlipid® N Infant or Vitlipid® N Adult).

As with all infusions, care should be taken to avoid complications of catherisation including air embolism and central venous thrombosis. Strict asepsis should be maintained especially in the immunosuppressed patient.

Hypertonic preparations such as amino acid solutions and concentrated glucose solutions are commonly infused into a central vein. Vaminolact may also be infused into a peripheral vein when given simultaneously with a fat emulsion (Intralipid) through the same cannula, since the reduced osmolality of the overall mixture may reduce the risk of thrombophlebitis.

For safe administration of intravenous fluids from non-collapsible containers, a giving set with integral airway is recommended.

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 substances 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.

Care must be exercised in the administration of large volume infusion fluids to patients with cardiac insufficiency. Amino acid infusions must also be administered with caution to patients with disturbances in protein metabolism. Hyperkalaemia, hypernatraemia and acidosis should be corrected prior to commencement of intravenous nutrition; serum electrolytes, blood glucose levels, acid base balance and fluid levels should be regularly monitored.
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).

4.5. Interactions 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.

Abnormal liver function tests have been observed during intravenous infusion, but these return to normal when artificial feeding is stopped. Cholestasis has been reported in some patients receiving intravenous nutrition.

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 via the Yellow Card scheme at www.mhra.gov.uk/yellowcard.

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 cases of suspicion of overdosage the infusion should be stopped. Emergency procedures should be general supportive measures, respiratory and cardiovascular. Close biochemical monitoring would be essential and specific abnormalities treated appropriately, perhaps by the careful infusion of hypotonic solutions and concomitant diuretic therapy, and administration of

sodium bicarbonate for metabolic acidosis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vaminolact is formulated to supply essential and non essential 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. Endogenous formation of taurine is either absent or limited in the neonate and due to the lack of necessary enzymes; taurine is considered an essential amino acid in the neonate. 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. Vaminolact also includes cysteine and tyrosine which seem to be essential for neonates.

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. Pre-clinical 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, Ph Eur.

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

Lightweight glass bottle (Ph Eur, Type II) sealed with a butyl rubber stopper containing 100 or 500 ml of solution.

Pack size:
12 x 100 ml
12 x 500 ml

10 x 100 ml
10 x 500 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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).

Do not use if the bottle is leaking or if the solution is cloudy or contains a precipitate. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Electrolyte requirements should be individually assessed.
All additions should be made aseptically.
The manufacturer can be contacted for full information on complete and balanced intravenous nutrition regimens.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT

8. MARKETING AUTHORISATION NUMBER(S)

PL 8828/0123

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 February 2009

10 DATE OF REVISION OF THE TEXT

27/04/2026