Summary of Product Characteristics
BENUTRION VE
(Amino acids with electrolytes, solution for infusion)

1. Name of the medicinal product

BENUTRION VE, solution for infusion.

2. Qualitative and quantitative composition

Each 250 mL contains:

Constituent	Amount per 250 mL
L-Isoleucine	0.628 g
L-Leucine	0.698 g
L-Lysine	0.523 g
L-Methionine	0.244 g
L-Phenylalanine	0.454 g
L-Threonine	0.436 g
L-Tryptophan	0.140 g
L-Valine	0.523 g
L-Arginine	0.872 g
L-Histidine	0.175 g
L-Alanine	2.314 g
L-Aspartic acid	1.012 g
N-Acetyl-L-cysteine	0.040 g
L-Glutamic acid	2.375 g
Glycine	0.962 g
L-Proline	1.047 g
N-Acetyl-L-tyrosine	0.086 g
Nicotinamide	0.015 g
Pyridoxine hydrochloride	0.010 g
Riboflavin 5'-phosphate sodium	0.625 mg
Potassium hydroxide	0.351 g
Sodium hydroxide	0.300 g
Calcium chloride dihydrate	0.184 g
Magnesium acetate tetrahydrate	0.134 g

Water for injections to 250 mL.

Electrolyte content:

Electrolyte	Concentration
Sodium (Na^+)	30 mmol/L
Potassium (K^+)	25 mmol/L
Calcium (Ca^{2+})	5 mmol/L
Magnesium (Mg^{2+})	2.5 mmol/L
Acetate	5 mmol/L
Chloride (Cl^-)	10 mmol/L

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Solution for infusion.

A clear, yellow solution.

4. Clinical particulars

4.1 Therapeutic indications

BENUTRION VE is a solution for the partial parenteral nutrition of premature infants and neonates, supplying amino acids (protein building blocks), electrolytes, water-soluble vitamins and water in situations where oral or enteral feeding is inadequate or impossible, in cases of increased protein requirements, protein deficiency or protein catabolism.

4.2 Posology and method of administration

Posology

Unless otherwise prescribed, the standard dose in neonates is 2.5 g of amino acids per kg body weight per day (corresponding to 50 mL/kg body weight/day). The dose should be adjusted according to the patient's protein requirements, fluid balance and clinical and laboratory monitoring.

Method of administration

For intravenous infusion. The infusion rate is 2–5 mL/kg body weight/hour. Administration through a paediatric infusion set with a micro-drop system is recommended. BENUTRION VE is suitable for total parenteral nutrition only when combined with energy (calorie) solutions supplied simultaneously in adequate amounts. If long-term administration is intended, vitamins should be substituted separately.

4.3 Contraindications

- Congenital disorders of amino acid metabolism.
- Hyperkalaemia.
- Advanced hepatic insufficiency.
- Renal insufficiency (in the absence of renal replacement therapy).
- Hyperhydration (fluid overload) states.

4.4 Special warnings and precautions for use

Use with care in patients with decompensated cardiac insufficiency. Shock, disturbances of the acid-base balance, and pre-renally induced oliguria or anuria should be corrected before commencing parenteral nutrition, and adequate renal function should be ensured. Serum electrolytes, fluid balance, acid-base status, blood glucose and, during prolonged administration, liver function should be monitored. The solution should be used only if it is clear and the container and seal are undamaged.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Not applicable, as the product is intended for the parenteral nutrition of premature infants and neonates.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Too rapid an infusion of amino acid solutions may lead to renal losses of amino acids and, in susceptible patients, to nausea, flushing and vomiting. Reactions that may occur in relation to the solution or the technique of administration include febrile response, infection at the site of injection,

venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolaemia. If an adverse reaction occurs, the infusion should be discontinued, appropriate treatment initiated and, where necessary, the remainder of the fluid retained for examination.

Reporting of suspected adverse reactions

Reporting 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 National Regulatory Authority.

4.9 Overdose

Overdose or too rapid an infusion may cause fluid and electrolyte disturbances, hypervolaemia and amino acid intolerance (nausea, vomiting, flushing). Management consists of stopping the infusion and providing supportive and symptomatic treatment with monitoring of fluid, electrolyte and acid-base status.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions for parenteral nutrition, amino acids with electrolytes. ATC code: B05BA10.

BENUTRION VE supplies a balanced mixture of essential and non-essential L-amino acids together with electrolytes and water-soluble vitamins in proportions appropriate to the metabolic requirements of premature infants and neonates. The amino acids serve as substrates for protein synthesis, reducing the breakdown of endogenous body protein and supporting a positive nitrogen balance when adequate non-protein energy is supplied concurrently. The accompanying electrolytes contribute to the maintenance of fluid, electrolyte and acid-base homeostasis, and the added vitamins (nicotinamide, pyridoxine and riboflavin) act as cofactors in intermediary metabolism.

5.2 Pharmacokinetic properties

The amino acids supplied are physiological substrates that enter the body's amino acid pools and are utilised for protein synthesis and intermediary metabolism in the same way as amino acids derived from dietary protein. The electrolytes are distributed and eliminated according to normal physiological mechanisms.

5.3 Preclinical safety data

No preclinical data of specific relevance to the prescriber are available beyond that reflected in other sections. The constituents are physiological amino acids, electrolytes and vitamins.

6. Pharmaceutical particulars

6.1 List of excipients

- Disodium edetate
- Sodium hydroxide (for pH adjustment)
- Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those for which compatibility has been established.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C, away from light. Do not freeze. Keep out of the reach and sight of children.

6.5 Nature and contents of container

Infusion glass bottle with a net content of 250 mL, presented in a box.

6.6 Special precautions for disposal and other handling

For single use only. Use only if the solution is clear and the container and seal are undamaged. Any unused portion should be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

PT Sanbe Farma, Jl. Taman Sari No. 10, Bandung 40116, Jawa Barat, Indonesia.

Manufacturer

PT Sanbe Farma (Unit 3), Jl. Industri Cimareme No. 8, Desa Cimareme, Kecamatan Ngamprah, Kabupaten Bandung Barat, Indonesia.

8. Marketing Authorisation Number

H2009/19987/167

9. Date of first authorisation / renewal of the authorisation

10. Date of revision of the text