

SUMMARY OF PRODUCT CHARACTERISTICS

Updated May 5th, 2026| PT Sanbe Farma, Indonesia

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

BENUTRION® VE Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 250 mL contains:

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 2H ₂ O	0.184 g

Magnesium Acetate	0.134 g
Water for Injection ad	250 mL
Na ⁺	30 mEq/L
K ⁺	25 mEq/L
Ca ⁺⁺	10 mEq/L
Mg ⁺⁺	5 mEq/L
Acetate ⁻	5 mEq/L
Cl ⁻	10 mEq/L

3. PHARMACEUTICAL FORM

Clear, yellow solution (not more intense from the Y₃ standard solution)

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

BENUTRION® VE is solution for the partial parenteral nutrition of prematures and infants. Supply of protein building blocks, electrolytes, vitamins and water in cases where oral food intake is either inadequate or impossible, in cases with increased protein requirements, protein deficiency or protein catabolism.

4.2 Posology and Method of Administration IV

Infusion:

Use of a Baby-dos infusion-transfusion set with a mini-drop system (60 drops = 1 g ± 0,1g).

Dosage unless otherwise prescribed, in neonates, standard dosage 2,5 g amno acids (corresponding to 50 mL/kg body weight/day).

Infusion Rate:

2-5 mL/kg body weight/hour or 2-5 drops/kg body weight/minute if the mini-drop system is used.

4.3 Contraindications

Patients with disturbed amino acid metabolism, hyperkalemia, advanced hepatic insufficiency, renal insufficiency due to kidney defects and hyperhydration conditions.

4.4 Special Warnings and Precautions for Use

Use with care in the presence of decompensated cardiac insufficiency; shock, disturbances of the acid-base balance, pre-renally-induced oliguria and anuria should be treated before commencing parenteral nutrition.

Ensure adequate renal function.

BENUTRION® VE is suitable for total parenteral nutrition if used in combination with calorie solutions which should be supplied simultaneously in adequate dosages.

If intended for long-term administration, vitamins should be substituted separately.

Use only if solution is clear and both container and seal undamaged.

4.5 Interaction with other Medicines and other forms of interaction No

relevant information is available or could be found.

4.6 Fertility, pregnancy and lactation Not

applicable.

4.7 Effect on ability to drive and use machines Not

applicable.

4.8 Undesirable effects

- Too rapid an infusion of amino acid solutions leads to renal losses, and in susceptible patients, nausea, flushing, etc.
- Reactions which may occur because of 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 hypervolemia.

- If an adverse reaction occurs, discontinue infusion. Initiate appropriate treatment and retain the remainder of the fluid for examination, if deemed necessary.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agents.

4.9 Overdose

No relevant information is available or could be found.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group : Amino acids and derivatives

ATC code : A16AA

L-Isoleucine:

They provide ingredients for the manufacturing of other essential biochemical components in the body, some of which are utilized for the production of energy, stimulants to the upper brain and helping you to be more alert.

L-Leucine:

As essential amino acid. (Claim) Leucine helps with the regulation of blood-sugar levels, the growth and repair of muscle tissue (such as bones, skin and muscles), growth hormone production, wound healing as well as energy regulation. It can assist to prevent the breakdown of muscle proteins that sometimes occur after trauma or severe stress. It may also be beneficial for individuals with phenylketonuria – a condition in which the body cannot metabolize the amino acid phenylalanine.

L-Lysine:

Insures the adequate absorption of calcium; helps form collagen (which makes up bone cartilage & connective tissue); aids in the production of antibodies, hormones

& enzymes. Recent studies have shown that Lysine may be effective against herpes by improving the balance of nutrients that reduce viral growth. A deficiency may result in tiredness, inability to concentrate, irritability, bloodshot eyes, retarded growth, hair loss, anemia & reproductive problems.

L-Methionine:

L-Methionine is a principle supplier for sulfur which prevents disorders of the hair, skin and nails; helps lower cholesterol levels by increasing the liver's production of lecithin; reduces liver fat and protects the kidneys; influences hair follicles and promotes hair growth. L-methionine may protect against the toxic effects of hepatotoxins such as acetaminophen. Methionine may have antioxidant activity.

L-Phenylalanine:

Used by the brain to produce Norepinephrine, a chemical that transmits signals between nerve cells and the brain; keeps you awake and alert, reduces hunger pains; functions as an antidepressant and helps improve memory.

L-Threonine:

L-Threonine is an essential amino acid that helps to maintain the proper protein balance in the body. It is important for the formation of collagen, elastin and tooth enamel and aids liver and lipotropic function when combined with aspartic acid and methionine.

L-Tryptophan:

Tryptophan is critical for the production of the body's proteins, enzymes and muscle tissue. It is also essential for the production of niacin, the synthesis of the neurotransmitter serotonin and melatonin. Tryptophan supplements can reduce anxiety and depression and has been shown to reduce the intensity of migraine headache. Other promising indications include the relief of chronic pain, reduction of impulsivity or mania and the treatment of obsessive or compulsive disorders. Tryptophan also appears to help the immune system and can reduce the risk of cardiac spasms. Tryptophan is marketed as a prescription drug (Tryptan) for those who do not seem to respond well to conventional antidepressants. It may be used to

treat those afflicted with seasonal affective disorder (a winter-onset depression). Tryptophan serves as the precursor for the synthesis of serotonin (5-hydroxytryptamine, 5-HT) and melatonin (N-acetyl-5-methoxytryptamine).

L-Valine:

They provide ingredients for the manufacturing of other essential biochemical components in the body, some of which are utilized for the production of energy, stimulants to the upper brain and helping you to be more alert.

L-Arginine:

Studies have shown that it has improved immune response to bacteria, viruses and tumor cells; promotes wound healing and regeneration of the liver; causes the release of growth hormones; considered crucial for optimal muscle growth and tissue repair.

L-Histidine:

Is found abundantly in hemoglobin; has been used in the treatment of rheumatoid arthritis, allergic disease, ulcers and anemia. A deficiency can cause poor hearing.

L-Alanine:

Is an important source of energy for muscle tissue, the brain and central nervous system; strengthens the immune system by producing antibodies; helping in the metabolism of sugars and organic acids.

L-Aspartic Acid:

L-aspartate is considered a non-essential amino acid, meaning that, under normal physiological conditions, sufficient amounts of the amino acid are synthesized in the body to meet the body's requirements. L-aspartate is formed by the transamination of the Krebs cycle intermediate oxaloacetate. The amino acid serves as a precursor for synthesis of proteins, oligopeptides, purines, pyrimidines, nucleic acids and L-arginine. L-aspartate is a glucogenic amino acid, and it can also promote energy production via its metabolism in the Krebs cycle. These latter

activities were the rationale for the claim that supplemental aspartate has an anti-fatigue effect in skeletal muscle, a claim that was never confirmed.

N-Acetyl-L-Cysteine:

NAC suppresses the “master signaling molecule” nuclear factor-kappaB (NFkB), which in turn prevents activation of multiple inflammatory mediators. NAC also regulates the gene for COX-2, the enzyme that produces pain- and inflammation-inducing prostaglandins in a wide array of chronic

conditions. NAC’s ability to replenish the intracellular glutathione supply and mitigate oxidative damage is a separate and equally powerful mechanism that affords protection against DNA damage and cancer development, even in smokers. NAC’s inhibition of inflammatory cytokine production is another mechanism credited with cancer reduction in various body tissues.

L-Glutamic Acid:

In addition to being one of the building blocks in protein synthesis, it is the most widespread neurotransmitter in brain function, as an excitatory neurotransmitter and as a precursor for the synthesis of GABA in GABAergic neurons.

L-Glycine:

One of the major inhibitory neurotransmitters in the mammalian CNS, predominantly active in the spinal cord and brain stem. Also acts as a modulator of excitatory amino acid transmission mediated by NMDA receptors. Also available as part of the NMDA Receptor – Glycine Site Tocris™ Non-essential amino acid for human development. An inhibitory neurotransmitter in spinal cord.

Allosteric regulator of NMDA receptors.

L-Proline:

L-Proline is a major amino acid found in cartilage and is important for maintaining youthful skin as well as repair of muscle, connective tissue and skin damage. It is also essential for the immune system, and for necessary balance of this formula. It is an essential component of collagen and is important for proper functioning of

joints and tendons. L-Proline is extremely important for the proper functioning of joints and tendons. Helps maintain and strengthen heart muscles.

N-Acetyl-L-Tyrosine:

N-acetyltyrosine is used as a high solubility precursor to Tyrosine used due to Tyrosine's poor solubility. It is deacetylated to form Tyrosine.

Nicotinamide:

No relevant information is available.

Pyridoxine Hydrochloride:

No relevant information is available.

Riboflavin 5'-Phosphate Sodium:

Riboflavin of vitamin B2 is an easily absorbed, water-soluble micronutrient with a key role in maintaining human health. Like the other B vitamins, it supports energy production by aiding in the metabolising of fats, carbohydrates, and proteins. Vitamin B2 is also required for red blood cell formation and respiration. It is essential for healthy skin, nails, hair growth and general good health, including regulating thyroid activity. Riboflavin also helps in the prevention or treatment of many types of eye disorders, including some cases of cataracts.

Potassium Hydroxide:

The corrosiveness of potassium hydroxide renders it a very useful agent in the decomposition/removal of soft tissue and hair removal. It is incorporated into some nail products, shaving creams, and soaps.

Sodium Hydroxide:

Sodium hydroxide 10% forms a strongly alkaline and caustic solution. As a caustic agent, it is used to destroy organic tissue by chemical action.

Calcium Chloride 2H₂O

Calcium is the fifth most abundant element in the body and the major fraction is in the bony structure. Calcium plays important physiological roles, many of which are poorly understood. It is essential for the functional integrity of the nervous and muscular system. It is necessary for normal cardiac function and is one of the factors that operates on the mechanisms involved in the coagulation of blood.

Magnesium Acetate Tetrahydrate:

Magnesium is an essential cofactor for many enzymatic reactions such as protein synthesis and ATP production. It also participates in adenylyl cyclase pathway and tyrosine kinase signalling pathways. Magnesium may also play a role in regulating glucose metabolism. It serves as an essential cation for a number of biochemical processes involved in nerve signaling, bone mineralization and muscle contractions.

5.2 Pharmacokinetic properties

No relevant information is available or could be found.

5.3 Preclinical safety data

No relevant information is available or could be found.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Edetate Disodium	: Chelating Agent
Sodium Hydroxide	: pH adjuster
Water for Injection	: Solvent

6.2 Incompatibilities

This section is not applicable because the drug product is an infusion dosage form and there is no reconstitution diluents required.

6.3 Shelf life

24 months.

6.4 Special Precaution for Storage

below 30°C, away from light

6.5 Nature and Contents of Containers

Box of infusion glass bottle with net contents of 250 mL.

6.6 Special Precaution for Disposal and other Handling

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

7. MARKETING AUTHORIZATION HOLDER

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9. MARKETING AUTHORIZATION NUMBER

H1009/19987/167

10. DATE OF FIRST AUTHORIZATION

April 7th, 2009

11. DATE OF REVISION

05/05/2026