NAME OF THE MEDICINAL PRODUCT

Aminoplasmal B. Braun 5% E Solution for Infusion

COMPOSITION

The solution for infusion contains:

	per 1 ml	per 250 ml	per 500 ml	per 1000 ml
Isoleucine	2.50 mg	0.63 g	1.25 g	2.50 g
Leucine	4.45 mg	1.11 g	2.23 g	4.45 g
Lysine hydrochloride (equivalent to lysine)	4.28 mg (3.43 mg)	1.07 g (0.86 g)	2.14 g (1.72 g)	4.28 g (3.43 g)
Methionine	2.20 mg	0.55 g	1.10 g	2.20 g
Phenylalanine	2.35 mg	0.59 g	1.18 g	2.35 g
Threonine	2.10 mg	0.53 g	1.05 g	2.10 g
Tryptophan	0.80 mg	0.20 g	0.40 g	0.80 g
Valine	3.10 mg	0.78 g	1.55 g	3.10 g
Arginine	5.75 mg	1.44 g	2.88 g	5.75 g
Histidine	1.50 mg	0.38 g	0.75 g	1.50 g
Alanine	5.25 mg	1.31 g	2.63 g	5.25 g
Glycine	6.00 mg	1.50 g	3.00 g	6.00 g
Aspartic acid	2.80 mg	0.70 g	1.40 g	2.80 g
Glutamic acid	3.60 mg	0.90 g	1.80 g	3.60 g
Proline	2.75 mg	0.69 g	1.38 g	2.75 g
Serine	1.15 mg	0.29 g	0.58 g	1.15 g
Tyrosine	0.40 mg	0.10 g	0.20 g	0.40 g
Sodium acetate trihydrate	1.361 mg	0.340 g	0.681 g	1.361 g
Potassium acetate	2.453 mg	0.613 g	1.227 g	2.453 g
Sodium chloride	0.964 mg	0.241 g	0.482 g	0.964 g
Sodium hydroxide	0.140 mg	0.035 g	0.070 g	0.140 g
Magnesium chloride hexahydrate	0.508 mg	0.127 g	0.254 g	0.508 g
Disodium phosphate dodecahydrate	3.581 mg	0.895 g	1.791 g	3.581 g

Electrolyte concentrations

Sodium	50	mmol/l
Potassium	25	mmol/l
Magnesium	2.5	mmol/l
Acetate	35	mmol/l
Chloride	45	mmol/l
Phosphate	10	mmol/l
Citrate	1.0 – 2.0	mmol/l

Total amino acids	50	g/l
Total nitrogen	7.9	g/l

Excipients: Acetylcysteine, citric acid monohydrate (for pH-adjustment), water for injections.

THERAPEUTIC INDICATIONS

Supply of amino acids and a limited amount of electrolytes for parenteral nutrition, when oral or enteral nutrition is impossible, insufficient or contraindicated. For adults, adolescents and children over 2 years of age.

CONTRAINDICATIONS

Hypersensitivity to the active substances or to any of the excipients.
Inborn errors of amino acid metabolism; severe circulation disorders with vital risk (e.g. shock); Hypoxia; metabolic acidosis; severe hepatic insufficiency; severe renal insufficiency in absence of renal replacement therapy; high and uncorrected plasma concentration of one of the electrolytes contained in the product; decompensated cardiac insufficiency; acute pulmonary oedema; hyperhydration.

The medicinal product must not be administered to newborn infants, infants and toddlers less than two years of age, because the amino acid composition does not properly meet the special requirements of this paediatric age group.

UNDESIRABLE EFFECTS

Undesirable effects that, however, are not specifically related to the product but to parenteral nutrition in general may occur, especially at the beginning of parenteral nutrition.

Undesirable effects are listed according to their frequencies as follows:

Uncommon: (≥ 1/1 000 to < 1/100)
Not known: (cannot be estimated from the available data)

Immune system disorders
Not known: Allergic reactions

Gastrointestinal disorders
Uncommon: Nausea, vomiting

General disorders and administration site conditions
Not known: Local reactions at infusion site, including local pain, venous irritation and occasionally thrombophlebitis.

WARNINGS

Keep out of the sight and reach of children.
For single use only. Discard container and unused contents after use.
The solution should only be used if the closure of the container is not damaged and if the solution is clear colourless to faintly straw-coloured, free from particles.

NOTE
Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

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