NAME OF THE MEDICINAL PRODUCT

Aminoplasmal 15% E Solution for Infusion

COMPOSITION

The solution for infusion contains:

	per 1 ml	per 500 ml	per 1000 ml
Isoleucine	5.850 mg	2.925 g	5.850 g
Leucine	11.40 mg	5.700 g	11.40 g
Lysine monohydrate	3.000 mg	1.500 g	3.000 g
(equivalent to lysine)	(2.671 mg)	(1.336 g)	(2.671 g)
Lysine hydrochloride	6.600 mg	3.300 g	6.600 g
(equivalent to lysine)	(5.281 mg)	(2.641 g)	(5.281 g)
Methionine	5.700 mg	2.850 g	5.700 g
Phenylalanine	5.700 mg	2.850 g	5.700 g
Threonine	5.400 mg	2.700 g	5.400 g
Tryptophan	2.100 mg	1.050 g	2.100 g
Valine	7.200 mg	3.600 g	7.200 g
Arginine	16.05 mg	8.025 g	16.05 g
Histidine	5.250 mg	2.625 g	5.250 g
Alanine	22.35 mg	11.18 g	22.35 g
Glycine	19.20 mg	9.600 g	19.20 g
Aspartic acid	7.950 mg	3.975 g	7.950 g
Acetylcysteine	0.500 mg	0.250 g	0.500 g
(equivalent to cysteine)	(0.371 mg)	(0.186 g)	(0.371 g)
Glutamic acid	16.20 mg	8.100 g	16.20 g
Proline	7.350 mg	3.675 g	7.350 g
Serine	3.000 mg	1.500 g	3.000 g
Tyrosine	0.500 mg	0.250 g	0.500 g
Potassium acetate	2.945 mg	1.473 g	2.945 g
Sodium dihydrogen phosphatedihydrate	1.404 mg	0.702 g	1.404 g
Magnesium acetatetetrahydrate	0.558 mg	0.279 g	0.558 g

Electrolyte concentrations		
Sodium	50	mmol/l
Potassium	30	mmol/l
Magnesium	2.6	mmol/l
Acetate	35	mmol/l
Chloride	36	mmol/l
Phosphate	9.0	mmol/l

Total amino acids	150	g/l
Total nitrogen	24.0	g/l

Excipients: Sodium hydroxide (for pH-adjustment), citric acid monohydrate (for pH-adjustment), water for injection.

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 impairment 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 edema, disturbances of the electrolyte and fluid balance.

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

WARNINGS

Keep out of the sight and reach of children.
For single use only. Discard container and unused contents after use.
Use only if solution is clear and colourless up to faintly straw-coloured and the bottle and its closure are undamaged.

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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