Directions for Use
B. Braun Melsungen AG · 34209 Melsungen, Germany

Aminoplasmal – 5 % E

Solution for Infusion

Composition
1000 ml of solution contain

Active substances:		
Isoleucine	2.55	g
Leucine	4.45	g
Lysine hydrochloride (equivalent to lysine 2.80 g)	3.50	g
Methionine	1.90	g
Phenylalanine	2.55	g
Threonine	2.05	g
Tryptophan	0.90	g
Valine	2.40	g
Arginine	4.60	g
Histidine	2.60	g
Glycine	3.95	g
Alanine	6.85	g
Proline	4.45	g
Aspartic acid	0.65	g
Asparagine monohydrate (equivalent to asparagine 1.64 g)	1.86	g
Acetylcysteine (equivalent to cysteine 0.25 g)	0.34	g
Glutamic acid	2.30	g
Ornithine hydrochloride (equivalent to ornithine 1.25 g)	1.60	g
Serine	1.20	g
Tyrosine	0.30	g
Acetyltyrosine (equivalent to tyrosine 0.35 g)	0.43	g
Sodium acetate trihydrate	3.95	g
Potassium acetate	2.45	g
Magnesium acetate tetrahydrate	0.56	g
Sodium dihydrogen phosphate dihydrate	1.40	g
Sodium hydroxide	0.20	g
Malic acid	1.01	g

Electrolyte concentrations:		
Sodium	43	mmol/l
Potassium	25	mmol/l
Magnesium	2.6	mmol/l
Acetate	59	mmol/l
Chloride	29	mmol/l
Phosphate	9.0	mmol/l
L-Malate	7.5	mmol/l
Total amino acids	50	g/l
Total nitrogen	8.0	g/l

Excipients:
Disodium edetate, water for injections

Pharmaceutical form
Solution for infusion
Clear, colourless or faintly straw-coloured aqueous solution

Caloric value	835	kJ/l ≙ 200 kcal/l
Osmolarity	590	mOsm/l
Acidity (titration to pH 7.4) approx.	18	mmol/l
pH	5.0 – 7.5	

Pharmaco-therapeutic group
Solutions for parenteral nutrition, combinations
ATC code: B05B A10

Indications
Supply of amino acids as a substrate for protein synthesis in parenteral nutrition, when oral or enteral nutrition is impossible, insufficient or contraindicated.

In parenteral nutrition, amino acid infusions should always be combined with adequate calorie supply, e. g. in the form of carbohydrate solutions.

Contraindications
- hypersensitivity to any of the ingredients present in the solution
- congenital abnormalities of amino acid metabolism
- severe circulatory disorders with vital risk (e.g. shock)
- hypoxia
- metabolic acidosis
- advanced liver disease
- severe renal insufficiency without access to haemofiltration or haemodialysis
- high and pathological plasma concentration of one of the electrolytes contained in the product
- uncompensated cardiac insufficiency
- acute pulmonary oedema
- hyperhydration.

This solution should not be administered to neonates, infants or children up to the completed 2nd year as the nutrient relations do not properly meet the special paediatric requirements.

Special warnings and precautions for use
This solution should only be administered after careful benefit-risk assessment in the presence of disorders of amino acid metabolism of other origin than stated under section 'contraindications'.

Care should be exercised in the administration of large volume infusion fluids to patients with cardiac insufficiency.

In patients with hepatic or renal insufficiency, the dose must be adjusted according to individual requirements.

Caution is to be exercised in patients with increased serum osmolarity.

Electrolyte and fluid imbalances such as hypotonic dehydration and hyponatraemia, should be corrected by adequate supply of fluid and electrolytes prior to parenteral nutrition.

Serum electrolytes, blood glucose, fluid balance, acid-base balance and renal function (BUN, creatinine) should be monitored regularly.

Monitoring should also include serum protein and liver function tests.

Aminoplasmal – 5 % E is applicable as part of a total parenteral nutrition regimen in combination with adequate amounts of energy supplements (carbohydrate solutions, fat emulsions), vitamins and trace elements.

If the solutions are administered in combination with other nutrient solutions, the possibility of peripheral venous infusion depends on the osmolarity of the resulting mixture.

The site of infusion should be checked daily for signs of inflammation or infection.

Pregnancy and lactation
Studies in pregnant or breast-feeding women have not been conducted with this medicinal product. There are no pre-clinical data regarding the administration of Aminoplasmal – 5 % E during pregnancy.

Aminoplasmal – 5 % E should therefore be administered with caution during pregnancy and lactation and only if deemed clearly indicated after assessment of its benefits and possible risks.

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Interactions
Pharmacological interactions are not known.

Dosage
The dosage is adjusted according to the individual need of amino acids, electrolytes and fluid, depending on the patient's clinical condition (nutritional status and/or degree of nitrogen catabolism due to underlying disease).

Adults and adolescents from 15th to 18th year of life:

Average daily dose:
20 – 40 ml/kg body weight (BW) ≙ 1.0 – 2.0 g of amino acids/kg BW,
≙ 1400 – 2800 ml for a patient of 70 kg BW

Maximum daily dose:
40 ml/kg BW ≙ 2.0 g of amino acids/kg BW,
≙ 140 g of amino acids for a patient of 70 kg BW
≙ 2800 ml for a patient of 70 kg BW

Maximum infusion and drop rate, respectively:
2.0 ml/kg BW/h ≙ 0.1 g of amino acids/kg BW/h,
≙ 45 drops/min for a patient of 70 kg BW
≙ 2.34 ml/min for a 70 kg patient

Children and adolescents up to 14th year of life:
The dosages for this age group as stated below are average values for guidance. The exact dosage should be adjusted individually according to age, developmental stage and prevailing disease.

Daily doses for:
3rd to 5th year of life: 30 ml/kg BW/day, corresponding to 1.5 g amino acids/kg BW
6th to 14th year of life: 20 ml/kg BW/day, corresponding to 1.0 g amino acids/kg BW

Maximum infusion rate:
2 ml/kg BW/h, corresponding to 0.1 g amino acids/kg BW/h

In the case of amino acid requirements of 1 g/kg BW/day or more, particular attention should be paid to the limitations of fluid input. To avoid fluid overload, amino acid solutions with higher amino acid content may have to be used in such situations.

Duration of use
The solution can be administered as long as there is an indication for parenteral nutrition.

Method of administration
Intravenous use

Aminoplasmal – 5 % E is only one component of parenteral nutrition. For complete parenteral nutrition, substrates for calorie supply, essential fatty acids, electrolytes, vitamins and trace elements must be administered together with amino acids.

Overdose
Overdose or a too high infusion rates may lead to intolerance reactions manifesting in the form of nausea, shivering, vomiting and renal amino acid losses.

Treatment
If intolerance reactions occur the amino acid infusion should be interrupted temporarily and resumed later at a lower infusion rate.

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.

Uncommon (≥ 1/1,000 to < 1/100):
Gastrointestinal disorders: nausea, vomiting
General disorders: headache, shivering, fever

Note:
Patients are advised to inform their doctor or pharmacist if they notice any adverse reaction in connection with the administration of this drug.

Expiry date
The product must not be used beyond the expiry date stated on the labelling.

Instructions for storage / use / handling
Keep out of reach and sight of children.

Keep the bottles in the outer carton in order to protect from light. Do not store above 25°C. Do not freeze.

Cool storage of the solution, below 15°C, may lead to formation of crystals, that can, however, be easily dissolved by gentle warming at 25°C until dissolution is complete. Shake container gently to ensure homogeneity.

Containers are for single use only. Discard any unused contents remaining after the end of the infusion.

The solution should only be used if the closure of the container is not damaged and if the solution is clear.

Use a sterile giving set for administration.

If in the setting of complete parenteral nutrition it is necessary to add other nutrients such as carbohydrates, lipids, vitamins and trace elements to this medicinal product, admixing must be performed under strict aseptic conditions. Mix well after admixture of any additive. Pay special attention to compatibility.

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