



Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Aminoplasmal B. Braun
10% E

Solution for Infusion

Composition

1000 ml solution for infusion contains:

– active substances:

Amino acids:

Isoleucine	5.00 g
Leucine	8.90 g
Lysine hydrochloride (equivalent to lysine 6.85 g)	8.56 g
Methionine	4.40 g
Phenylalanine	4.70 g
Threonine	4.20 g
Tryptophan	1.60 g
Valine	6.20 g
Arginine	11.50 g
Histidine	3.00 g
Alanine	10.50 g
Glycine	12.00 g
Aspartic acid	5.60 g
Glutamic acid	7.20 g
Proline	5.50 g
Serine	2.30 g
Tyrosine	0.40 g

Electrolytes:

Sodium acetate trihydrate	2.858 g
Sodium hydroxide	0.360 g
Potassium acetate	2.453 g
Magnesium chloride hexahydrate	0.508 g
Disodium hydrogen phosphate dodecahydrate	3.581 g

– excipients:

Acetylcysteine	
Citric acid monohydrate	
Water for injection	
Nitrogen (protective gas)	

Amino acid content	100 g/l
Total nitrogen content	15.8 g/l
Caloric value:	1675 kJ/l \triangle 400 kcal/l
Theoretical osmolality:	1021 mOsm/l
Titration acidity (pH 7.4):	approx. 26 mmol/l
pH:	5.7–6.3

Electrolyte concentrations:

Sodium	50 mmol/l
Potassium	25 mmol/l
Magnesium	2.5 mmol/l
Acetate	46 mmol/l
Chloride	52 mmol/l
Phosphate	10 mmol/l
Citrate	2.0 mmol/l

Pharmaceutical form and contents

Solution for infusion in glass bottles of 250 ml, 500 ml, 1000 ml

Available pack sizes

10 x 250 ml
10 x 500 ml
6 x 1000 ml

Pharmaco–therapeutic category

Solutions for parenteral nutrition, combinations

Marketing authorisation holder and manufacturer

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen, Germany

Postal address
34209 Melsungen, Germany

Indications

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

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

Contraindications

- Hypersensitivity to an amino acid present in the solution
- Congenital abnormalities of amino acid metabolism
- Severe circulation disorders with vital risk (e.g. shock)
- Hypoxia
- Metabolic acidosis
- Advanced liver disease
- Severe renal insufficiency without treatment by haemodialysis or haemofiltration
- High and pathological plasma concentration of any of the electrolytes included in the product
- Use in children under 2 years of age
- General contraindications for infusion therapy:
 - uncompensated cardiac insufficiency
 - acute pulmonary oedema
 - hyperhydration

Pregnancy and lactation

Studies in pregnant or breastfeeding women have not been conducted with this medicinal product. There are no pre-clinical data regarding the administration of Aminoplasmal B. Braun 10% E during pregnancy.

Aminoplasmal B. Braun 10% E should therefore be administered with caution during pregnancy and lactation only if clearly indicated and after carrying out a benefit/risk analysis.

Special warnings and precautions for use

Aminoplasmal B. Braun 10% E should only be administered after careful benefit/risk assessment in the presence of disorders of acid metabolism of other origin than stated under "**Contraindications**".

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

Caution should be exercised in patients with increased serum osmolality.

Hypotonic dehydration 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.

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

Aminoplasmal B. Braun 10% E can be used as part of a total parenteral nutrition regimen in combination with adequate amounts of energy supplements (carbohydrate solutions, fat emulsions), vitamins, trace elements and electrolytes.

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



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Schwarz
210x297 mm
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Lätus: 3721
Indien

