452/12609663/1012

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Amino Acids Crystalline

Aminoplasmal B. Braun 10% E

Solution for Infusion

Formulation

Each 1000 mL contains:

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 phosphate dodecahydrate	3.581 g

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

Excipients:

Acetylcysteine, citric acid monohydrate and water for injections.

Pharmaceutical form

Solution for infusion

Amino acid content	100 g/L
Nitrogen content	15.8 g/L
Energy	1675 kJ/L ≙ 400 kcal/L
Theoretical osmolarity	1021 mOsm/L
Titration acidity (pH 7.4), approximately	26 mmol/L
pH	5.7–6.3

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 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.

Special warnings and precautions for use

Amino Acids Crystalline (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 osmolarity.

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.

Amino Acids Crystalline (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 site of infusion should be checked daily for signs of inflammation or infection.

Interactions

None known.

Pregnancy and lactation

Studies in pregnant or breastfeeding women have not been conducted with this medicinal product. There are no preclinical data regarding the administration of Amino Acids Crystalline (Aminoplasmal B. Braun 10% E) during pregnancy.

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Amino Acids Crystalline (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.

Dosage
The dosage is adjusted according to the individual need for amino acids, electrolytes, and fluids depending on the clinical condition of the patient (nutritional status and degree of catabolism due to underlying disease).

Adults and adolescents from 15 to 17 years:
Daily dose:
10 - 20 mL/kg body weight (BW)
≙ 1.0–2.0 g amino acids/kg BW
≙ 700–1400 mL for 70 kg BW

Maximum daily dose:
20 mL/kg BW ≙ 2.0 g amino acids/kg BW
≙ 140 g amino acids for 70 kg BW
≙ 1400 mL for 70 kg BW

Maximum infusion or drop rate:
1 mL/kg per BW and per hour
≙ 0.1 g amino acids/kg per BW and per hour
≙ 25 drops/min for 70 kg BW
≙ 1.17 mL/min for 70 kg BW

Children and adolescents up to 14 years:
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 dose for 3rd to 5rd year of age:
15 mL/kg BW ≙ 1.5 g amino acids/kg BW

Daily dose for 6th to 14th year of age:
10 mL/kg BW ≙ 1.0 g amino acids/kg BW

Maximum infusion rate:
1 mL/kg per BW and per hour ≙ 0.1 g amino acids/kg per BW and per hour

Duration of use
Amino Acids Crystalline (Aminoplasmal B. Braun 10% E) may be administered for as long as there is an indication for parenteral nutrition.
Amino Acids Crystalline (Aminoplasmal B. Braun 10% E) is only one component of parenteral nutrition. In parenteral nutrition, amino acid supply must be combined with supply of calorie sources, essential fatty acids, electrolytes, vitamins, and trace elements.

Method of administration
Intravenous use (central venous infusion).

Overdose

Symptoms
Overdose or too rapid infusion may lead to intolerance reactions and may manifest as nausea, shivering, vomiting and renal amino acid losses.

Emergency treatment, antidotes
If intolerance reactions occur, the amino acid infusion should be interrupted and resumed later on at a lower infusion rate.

Adverse effects
Adverse effects are not specifically related to this product but they can occur as a result of parenteral nutrition, particularly at the beginning of the treatment.

Uncommon (affecting 1 to 10 treated patients in a 1,000)
Gastrointestinal disorders: nausea, vomiting
General disorders: headache, shivering, fever

Note
Patients should inform their doctor or pharmacist if they notice any adverse effect not mentioned in this leaflet.

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

Special precautions for storage
Keep out of the reach and sight of children.
Do not store above 25 °C. Do not freeze.
Keep the bottle in the outer carton in order to protect from light.
Cool storage, 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.
The solution should only be used if the bottle and its closure is not damaged and if the solution is clear.
A sterile infusion set must be used.
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.
From the microbiological point of view, mixtures must be administered immediately. If not administered immediately, storage times and conditions prior to use are the responsibility of the user. Mixtures with other components should not usually be stored longer than 24 hours at 2°-8°C unless mixing has taken place under controlled and validated aseptic conditions.
For single use only. After infusion any residual product must be disposed of.

Caution
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription

Availability:
Glass bottles of 500 mL, available in packs of 10 bottles

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