1 NAME OF THE MEDICINAL PRODUCT

Aminoplasmal B. Braun 10 % E solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of solution contain

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
Total amino acids	100 g/l
Total nitrogen	15.8 g/l
Caloric value:	1675 kJ/l = 400 kcal/l
Theoretical osmolarity:	1021 mOsm/l
Titration acidity (to pH 7.4):	approx. 26 mmol/l
pH:	5.7 – 6.3

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic 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 adequate calorie supply, e.g. in the form of carbohydrate infusions.

4.2 Posology and method of administration

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

Adults and adolescents from 15 to 17 years:

Average daily dose:
10-20 ml /kg body weight (BW) ≙ 1.0–2.0 g amino acids/kg BW
≙ 700–1400 ml for a 70 kg patient

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

Maximum infusion and drop rates, respectively:
1 ml/kg BW/h ≙ 0.1 g amino acids/kg BW/h
≙ 25 drops/min for a 70 kg patient
≙ 1.17 ml/min for a 70 kg patient

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 5th year of life:
15 ml/kg BW ≙ 1.5 g amino acids/kg BW

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

Maximum Infusion rate:
1 ml/kg BW/h ≙ 0.1 g amino acids/kg BW/h

Method of administration and duration of use

Intravenous use (central venous infusion).

It can be administered as long as there is an indication for parenteral nutrition.

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.

4.3 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 access to haemofiltration or haemodialysis
- High and pathological plasma concentration of one of the electrolytes included in the product
- Children under 2 years of age
- General contraindications of infusion therapy:
  - uncompensated cardiac insufficiency
  - acute pulmonary oedema
  - hyperhydration

4.4 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 amino acid metabolism of other origin than stated under section 4.3

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.

Aminoplasmal B. Braun 10 % 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.

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

4.5 Interactions with other medicinal products and other forms of interaction

None known

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4.6 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 B. Braun 10 % E during pregnancy.

Aminoplasmal B. Braun 10 % 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.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 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 (< 1:100, ≥ 1:1000 of treated patients):

Gastrointestinal disorders: nausea, vomiting

General disorders: headache, shivering, fever

4.9 Overdose

Symptoms

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

Treatment

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions for parenteral nutrition, ATC-Code B05BA10.

The aim of parenteral nutrition is the supply of all nutrients necessary for the growth, maintenance and regeneration of body tissues etc.

Amino acids are of special importance as they partly are essential for protein synthesis. Intravenously administered amino acids are incorporated in the respective intravascular and intracellular amino acid pools. Both endogenous and exogenous amino acids serve as substrate for the synthesis of functional and structural proteins.

To prevent the metabolisation of amino acids for energy production, and also to fuel the other energy consuming processes in the organism, simultaneous energy supply (in the form of carbohydrate or fat) is necessary.

5.2 Pharmacokinetic properties

Because Aminoplasmal B. Braun 10 % E is infused intravenously, the bioavailability of the amino acids and electrolytes contained in the solution is 100 %.

The composition of Aminoplasmal B. Braun 10 % E is based upon the results of clinical investigations of the metabolism if intravenously administered amino acids. The quantities of the amino acids contained in Aminoplasmal B. Braun 10 % E have been chosen so that a homogenous increase of the concentrations of all plasma amino acids is achieved. The physiological relations of plasma amino acids, i. e. the amino acid homeostasis is thus maintained during infusion of Aminoplasmal B. Braun 10 % E.

Amino acids, that do not enter protein synthesis, are metabolized as follows. The amino group is separated from the carbon skeleton by transamination. The carbon chain is either oxidized directly to CO_2 or utilized as substrate for gluconeogenesis in the liver. The amino group is also metabolized in the liver to urea.

5.3 Preclinical safety data

Preclinical studies have not been performed with this medicinal product. Aminoplasmal B. Braun 10 % E only contains amino acids and electrolytes that are substrates of human metabolism.

Therefore, no toxic reactions are expected to occur as long as the indications, contraindications and dosage recommendations are duly observed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetylcysteine,
Citric acid monohydrate,
Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf Life

Shelf life in the unopened container

3 years

Shelf life after first opening the container

The medicinal product should be used immediately.

Shelf life after mixing with other components

From the microbiological point of view, mixtures should be administered immediately after preparation. If not administered immediately, storage times and conditions of mixtures prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C – 8 °C, unless mixing has taken place under controlled and validated aseptic conditions.

6.4 Special Precautions for Storage

Keep the container in the outer carton in order to protect from light.

Do not freeze.

Do not store above 25 °C.

6.5 Nature and content of container

Bottles of colourless glass (type II), sealed with chlorobutyl-rubber stoppers

Contents: 250 ml, available in packs of 10 bottles
500 ml, available in packs of 10 bottles
1000 ml, available in packs of 6 bottles

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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.

7 MANUFACTURER

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8 LICENSE HOLDER

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