Aminoplasmal® B. Braun 10%

Solution for infusion

1 NAME OF THE MEDICINAL PRODUCT
Aminoplasmal® B. Braun 10% solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
1000 ml of solution contain

Amino acids:
- Isoleucine: 5.00 g
- Leucine: 8.90 g
- Lysine: 5.74 g (equivalent to Lysine, 4.07 g)
- Lysine monohydrate: 3.12 g (equivalent to Lysine, 2.78 g)
- Methionine: 4.40 g
- Phenylalanine: 4.20 g
- Threonine: 4.20 g
- Tryptophan: 1.60 g
- Valine: 6.20 g
- Arginine: 15.50 g
- Histidine: 3.00 g
- Alanine: 10.50 g
- Glycine: 12.00 g
- Aspartic acid: 7.20 g
- Glutamic acid: 5.60 g
- Proline: 5.50 g
- Serine: 2.30 g
- Tyrosine: 0.40 g
- Total amino acids: 100 g/l
- Total nitrogen: 15.8 g/l
- Caloric value: 1675 kJ/l = 400 kcal/l
- Theoretical osmolarity: 864 mOsm/l
- pH: 5.7 - 6.3
- Electrolyte concentrations:
  - Citrate: 28 mmol/l
  - Acetate: 2 mmol/l
- Total nitrogen: 15.8 g/l
- pH: 5.7 - 6.3
- Electrolytes: sodium citrate 28 mmol/l

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 carbohydrate supply, e.g. in the form of carbohydrate infusions.

4.2 Dosage and method of administration
The dosage is adjusted according to the individual need of amino acids 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: 1 ml/kg BW/h
  - 0.1 g amino acids/kg BW
  - 700 - 1400 ml for a 70 kg patient

Maximum daily dose:
- 10 ml/kg BW
- 1.5 g amino acids/kg BW
- 140 g amino acids for a 70 kg patient
- 1400 ml for a 70 kg patient

Children and adolescents up to 17 years:

- Daily dose for 3rd to 5th year of life: 1 ml/kg BW/h
- 0.1 g amino acids/kg BW
- 700–1400 ml for a 70 kg patient

Maximum infusion and drop rates, respectively:
- 1.0 g amino acids/kg BW/h
- 140 g amino acids for a 70 kg patient
- 1400 ml for a 70 kg patient
- 25 drops/min for a 70 kg patient
- 1.17 ml/min for a 70 kg patient

Maximum daily dose:
- 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
- In patients of all ages
- Maximum duration is 28 days
- In patients with increased serum osmolarity
- In patients with liver or renal insufficiency

Supplementations (carbohydrate solutions, fat emulsions), vitamins, trace elements.

Intravenous use (central venous infusion).

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% 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

Hypokalaemia and/or hyponatraemia adequate amounts of potassium and/or sodium should be supplied.

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

Children under 2 years of age
- General contraindications of infusion therapy:
  - uncompensated cardiac insufficiency
  - acute pulmonary oedema
  - hyperhydration

4.3 Contraindication
- 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

4.5 HYPERSENSITIVITY REACTIONS
- Cardiovascular collapse
- Anaphylactoid reactions
- Anaphylactic reactions
- Immediate reactions
- Delayed reactions
- Other reactions

4.6 OVERDOSAGE
Treatment of overdose:
- General measures
- Renal function (BUN, creatinine) should be monitored regularly.
- Monitoring should also include serum protein and liver function tests.
- Fluid, electrolytes prior to parenteral nutrition.
- Hypotonic dehydration should be corrected by adequate supply of fluid and electrolytes.
- 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% is applicable 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.

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4.5 Interactions with other medicinal products and other forms of interaction
None known.

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 % during pregnancy.
Aminoplasmal B. Braun 10 % 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 parental 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 nausea, shivering, 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 B05B A01.
The aim of parentreral 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 metabolism 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 % is infused intravenously, the bioavailability of the amino acids contained in the solution is 100 %.
The composition of Aminoplasmal B. Braun 10 % 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 % have been chosen so that a homogenous increase of 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 metabolism 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.

5.3 Preclinical safety data
Preclinical studies have not been performed with this medicinal product. Aminoplasmal B. Braun 10 % only contains amino acids 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
SheLLf iLLe in the unopened container 3 years.

SheLLf iLLe afTeR fIrST oPenInG the conTainEr
The medicinal product should be used immediately.
SheLLf iLLe afTeR MiXInG with oTher conTainErS
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.

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.

6.5 Nature and content of container

Bottles of coloours 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 MARKETING AUTHORISATION HOLDER
B. Braun Melsungen AG
Carl-Braun-Straße 1, 34209 Melsungen

8 MARKETING AUTHORISATION NUMBER(S)
67-188-12 (500 ml bottle)
68-188-12 (1000 ml bottle)

9 DATE OF FIRST AUTHORISATION
01.01.2012

10 DATE OF REVISION OF THE TEXT
September 2010

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