SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Aminoplasmal Paediatric 10% Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The solution for infusion contains:

	per 1 ml	**per 100 ml**	**per 250 ml**
Isoleucine	5.10 mg	0.51 g	1.28 g
Leucine	7.60 mg	0.76 g	1.90 g
Lysine monohydrate (equivalent to lysine)	9.88 mg (8.80 mg)	0.99 g (0.88 g)	2.47 g (2.20 g)
Methionine	2.00 mg	0.20 g	0.50 g
Phenylalanine	3.10 mg	0.31 g	0.78 g
Threonine	5.10 mg	0.51 g	1.28 g
Tryptophan	4.00 mg	0.40 g	1.00 g
Valine	6.10 mg	0.61 g	1.53 g
Arginine	9.10 mg	0.91 g	2.28 g
Histidine	4.60 mg	0.46 g	1.15 g
Alanine	15.90 mg	1.59 g	3.98 g
Glycine	2.00 mg	0.20 g	0.50 g
Aspartic acid	6.60 mg	0.66 g	1.65 g
Glutamic acid	9.30 mg	0.93 g	2.33 g
Proline	6.10 mg	0.61 g	1.53 g
Serine	2.00 mg	0.20 g	0.50 g
N-Acetyltyrosine (equivalent to tyrosine)	1.30 mg (1.06 mg)	0.13 g (0.11 g)	0.33 g (0.27 g)
Acetylcysteine (equivalent to cysteine)	0.700 mg (0.520 mg)	0.070 g (0.052 g)	0.175 g (0.13 g)
Taurine	0.300 mg	0.030 g	0.075 g

Total amino acids	0.1 g	10 g	25 g
Total nitrogen	0.0152 g	1.52 g	3.8 g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless up to light yellow solution, practically free from visible particles.

Energy [kJ/l (kcal/l)]	1700 (406)
Theoretical osmolarity [mOsm/l]	790
Acidity (titration to pH 7.4) [mmol NaOH/l]	23
pH	approx. 6.1

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Supply of amino acids for parenteral nutrition in combination with energy (glucose and lipids) and electrolytes containing solutions, when oral or enteral nutrition is impossible, insufficient or contraindicated.
The solution is indicated for newborn infants, term and preterm infants and toddlers and children.

4.2 Posology and method of administration

Posology

Paediatric population

The dosages for the age group stated below are average values for guidance. The exact dosage should be adjusted individually according to age, developmental stage and prevailing disease. Dosing should be commenced below target infusion rate value and be increased to target value within the first hour.

Parenteral amino acid supply considered adequate for most paediatric patients:

Daily dose for preterm newborn infants:

First day of life
≥ 1.5 g amino acids/kg body weight ≥ 15 ml /kg body weight

From day 2 onwards
2.5 – 3.5 g amino acids/kg body weight 25 – 35 ml /kg body weight

Daily dose for term newborn infants (0 – 27 days):
1.5 - 3.0 g /kg body weight 15 - 30 ml/kg body weight.

Daily dose for infants and toddlers (1 month to less than 3 years):
1.0 - 2.5 g /kg body weight 10 - 25 ml/kg body weight

Daily dose for children (3 to less than 12 years):
1.0 - 2.0 g/kg body weight 10 – 20 ml/kg body weight

Critically ill children: For critically ill patients the advisable amino acid intake may be higher (up to 3.0 g amino acids/kg body weight per day).

Patients with renal/hepatic impairment
The doses should be adjusted individually in patients with hepatic or renal insufficiency (see also section 4.4). Aminoplasmal Paediatric 10% is contraindicated in severe hepatic insufficiency and severe renal insufficiency in absence of renal replacement therapy (see section 4.3).

Duration of use
This solution can be administered as long as parenteral nutrition is indicated.

Method of administration
Intravenous use.
For central venous infusion only.

When used in infants aged from preterm to 2 years old, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see sections 4.4, 6.3 and 6.6). During preparation of mixtures a light protecting overwrap might not be suitable. Nevertheless, attention should be paid to reduce light exposure as much as possible during preparation of mixtures.

4.3 Contraindications

- Hypersensitivity to any of the active substance(s) or to any of the excipients listed in section 6.1
- Inborn errors of amino acid metabolism
- Severe circulation disorders with vital risk (e.g. shock)
- Hypoxia
- Metabolic acidosis
- Severe hepatic insufficiency
- Severe renal insufficiency in absence of renal replacement therapy
- Decompensated cardiac insufficiency
- Acute pulmonary oedema
- Disturbances of the electrolyte and fluid balance

4.4 Special warnings and precautions for use

The medicinal product 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.

Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. When used in infants aged from preterm to 2 years old, Aminoplasmal Paediatric 10% should be protected from ambient light exposure until administration is completed (see sections 4.2, 6.3 and 6.6). During preparation of mixtures a light protecting overwrap might not be suitable. Nevertheless, attention should be paid to reduce light exposure as much as possible during preparation of mixtures.

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

Caution should be exercised in patients with increased serum osmolarity.

Disturbances of fluid and electrolyte balance (e.g. hypotonic dehydration, hyponatraemia, hypokalaemia) should be corrected prior to the administration of parenteral nutrition.

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

Monitoring should also include serum protein and liver function tests.

In patients with renal insufficiency, the dose must be carefully adjusted according to individual needs, severity of organ insufficiency and the kind of instituted renal replacement therapy (haemodialysis, haemofiltration etc.).

In patients with hepatic insufficiency, the dose must be carefully adjusted according to individual needs and severity of organ insufficiency.

Amino acid solutions are only one component of parenteral nutrition. For complete parenteral nutrition, substrates for non-protein energy supply, essential fatty acids, electrolytes, vitamins, fluids and trace elements must be administered together with amino acids.

Paediatric formulations should be used in the case of micronutrients.

During long-term use (several weeks), the blood count and coagulation factors should be monitored more carefully.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Not relevant, as Aminoplasmal Paediatric 10% is intended for use in infants, toddlers and children only.

4.7 Effects on ability to drive and use machines

Not relevant, as Aminoplasmal Paediatric 10% is intended for use in infants, toddlers and children only.

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.

Undesirable effects are listed according to their frequencies as follows:
Very common (≥ 1/10)

Common	(≥ 1/100 to < 1/10)
Uncommon	(≥ 1/1,000 to < 1/100)
Rare	(≥ 1/10,000 to < 1/1,000)
Very rare	(< 1/10,000)
Not known	(cannot be estimated from the available data)

Immune system disorders
Not known: Allergic reactions

Gastrointestinal disorders
Uncommon: Nausea, vomiting

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions viathe MHRA Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of fluid overdose
Overdose or too high infusion rates may lead to hyperhydration, electrolyte imbalance and pulmonary oedema.

Symptoms of amino acid overdose
Overdose or too high infusion rates may lead to intolerance reactions manifesting in the form of sickness, vomiting, shivering, headache, metabolic acidosis, hyperammonaemia and renal amino acid losses.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Blood substitutes and perfusion solutions, i.v. solutions for parenteral nutrition, amino acids. ATC code: B05BA01

Mechanism of action
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 non-protein energy supply (in the form of carbohydrates or fats) is necessary.

5.2 Pharmacokinetic properties

Absorption
Because this medicinal product is infused intravenously, the bio-availability of the amino acids contained in the solution is 100%.

Distribution
Amino acids are incorporated in a variety of proteins in different tissues of the body. In addition each amino acid is present as free amino acid in the blood and inside cells.

The composition of the amino acid solution is based upon the results of clinical investigations of the metabolism of intravenously administered amino acids. The quantities of the amino acids contained in the solution have been chosen so that a homogenous increase of the concentrations of all plasma amino acids is achieved. The physiological ratios of plasma amino acids, i.e. the amino acid homeostasis, are thus maintained during infusion of the medicinal product.

Normal foetal growth and development depend on a continuous supply of amino acids from the mother to the foetus. The placenta is responsible for the transfer of amino acids between the two circulations.

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

Elimination
Only minor amounts of amino acids are excreted unchanged in the urine.

5.3 Preclinical safety data

Non-clinical studies have not been performed with Aminoplasmal Paediatric 10%. The amino acids contained in Aminoplasmal Paediatric 10% are substances, which occur naturally in the organism.

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

Citric acid monohydrate (for pH-adjustment)
Water for injection

6.2 Incompatibilities

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

6.3 Shelf life

Unopened (bag in overwrap)
2 years

After first opening
The medicinal product should be used immediately.
When used in infants aged from preterm to 2 years old, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see sections 4.2, 4.4 and 6.6).

During preparation of mixtures
A light protecting overwrap during preparation of mixtures might not be suitable. Nevertheless, attention should be paid to reduce light exposure as much as possible during preparation of mixtures.

After admixture of additives
From a microbiological point of view, mixtures should be administered immediately after preparation. If not used 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

This medicinal product does not require any special storage conditions.

Do not freeze.

6.5 Nature and contents of container

Aminoplasmal Paediatric 10% is supplied in mono chamber plastic bags made from a transparent multilayer foil (Polypropylene, Styrene Ethylene Butylene Styrene (SEBS) and Copolyester ether). The inner layer in contact with the solution consists of polypropylene. The bags contain 100 ml or 250 ml.

The bag is packed in a protective overwrap. An oxygen absorber and an oxygen indicator are placed between the bag and the overwrap; the oxygen indicator is a thermoformed blister and contains the oxygen sensitive dye resorufin sodium; the oxygen absorber sachet is made of inert material and contains iron powder (activated), electrolyte materials and activated carbon (Figure A).

Pack sizes: 12 x 100 ml and 12 x 250 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Containers are for single use only. Discard overwrap, oxygen indicator, oxygen absorber, container and any unused contents after use.

Before opening the overwrap, check the colour of the oxygen indicator (see Figure A). Do not use if the oxygen indicator turned pink. Use only if the oxygen indicator is yellow.

Only to be used if the solution is clear, colourless up to light yellow, practically free from visible particles and the bag and its closure are undamaged.

When used in infants aged from preterm to 2 years, parenteral nutrition solutions containing Aminoplasmal Paediatric 10% should be protected from light exposure, until administration is completed. Exposure of such solutions to ambient light, especially after admixture with trace elements and/ or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure (see sections 4.2, 4.4 and 6.3).
During preparation of mixtures a light protecting overwrap might not be suitable. Nevertheless, attention should be paid to reduce light exposure as much as possible during preparation of mixtures.

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, electrolytes 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.

- Glucose: stability has been demonstrated up to a total quantity of 150 g/l of glucose in the mixture.

- Electrolytes:

  Without containing lipids: stability has been demonstrated up to a total quantity of 200 mmol/l of sodium + potassium (sum), 5 mmol/l of magnesium and 20 mmol/l of calcium in the mixture.
  With containing lipids: stability has been demonstrated up to a total quantity of 200 mmol/l of sodium + potassium (sum), 5 mmol/l of magnesium and 10 mmol/l of calcium in the mixture.

- Lipids: stability has been demonstrated up to a total quantity of 25 g/l of lipid emulsion in the mixture.

- Trace elements and vitamins: stability has been demonstrated with commercially available multi-trace elements and multi-vitamins (e.g. Peditrace, Vitalipid Infant, Soluvit N) up to the standard dosage recommended by the respective manufacturer of the micronutrient.

Aminoplasmal Paediatric 10%: Handling

Figure A: Bag and Overwrap

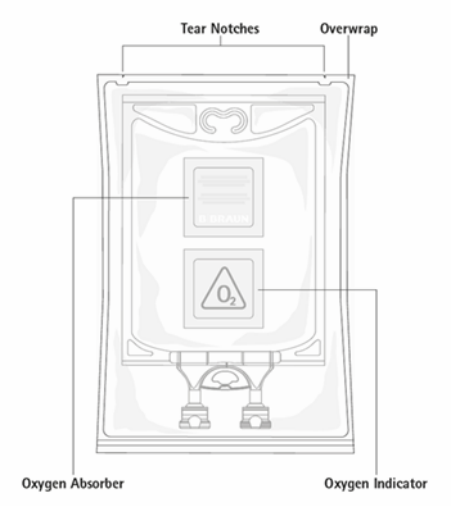
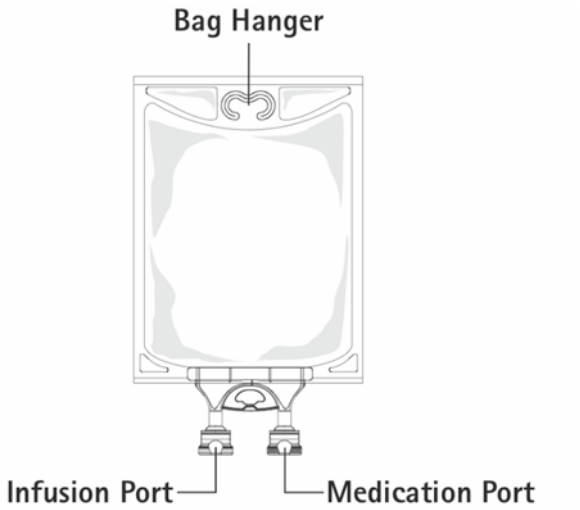
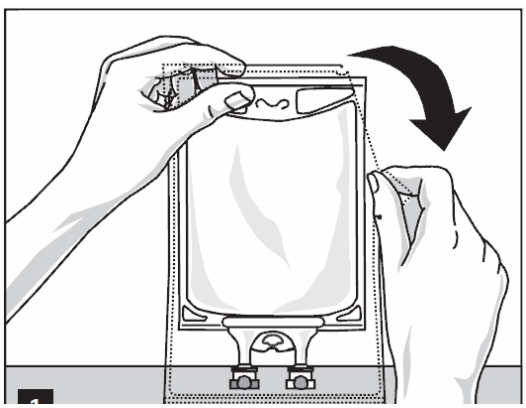


Figure B: Bag

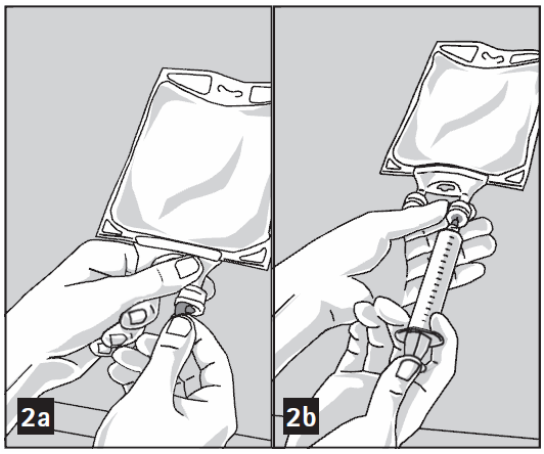


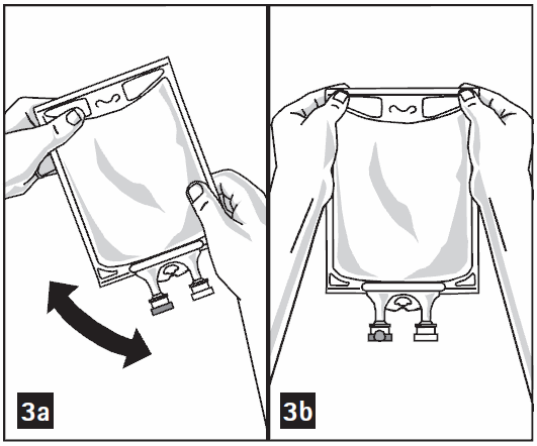


To Open:
Remove the bag from its protective overwrap starting from the tear notches on top and remove solution container (figure 1).
Discard overwrap, oxygen indicator and oxygen absorber.

Check for leakages. If bag leaks, discard product as sterility may be impaired.

To Add Medication:



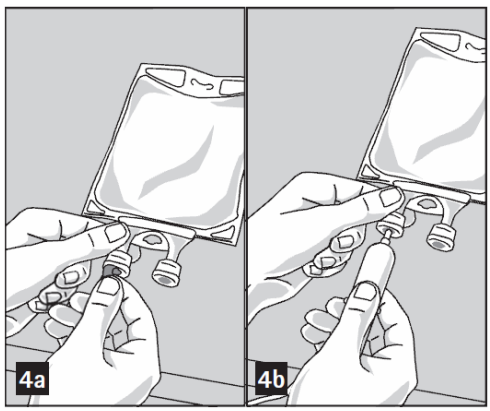


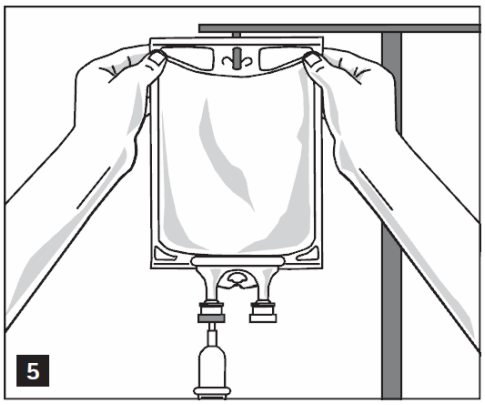
Admixtures must be prepared following strict aseptic techniques.
Compatible supplemental medication may be added through the medication port (transparent colour).

1. Prepare medication port (transparent colour) by removal of aluminium foil (figure 2a). Please note: The area underneath the foil of the medication port is sterile.
2. Puncture resealable medication port and inject additive(s) (figure 2b).
3. Mix solution and medication thoroughly (figure 3a).
4. Medication port may be swabbed with disinfection agent (e.g. iso-propanol) before re-puncturing.
5. Check admixture visually for particulate matter (figure 3b).

Preparation for Administration:

1. Remove aluminium foil of infusion port (green colour) at the bottom of container (figure 4a) and attach administration set (figure 4b): use non-vented infusion set or close air vent on a vented set. Follow directions for use of the infusion set. Please note: The area underneath the foil of the infusion port is sterile.
2. Hang bag on an i.v. pole (figure 5).





Additional Information:
Container is PVC-free, DEHP-free, latex-free

7 MARKETING AUTHORISATION HOLDER

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