

## Directions for Use

B. Braun Melsungen AG · Carl-Braun-Straße 1, 34212 Melsungen, Germany

# Aminoplasmal® 15%

## Solution for Infusion

### Composition

The solution for infusion contains

	per 1 ml	per 500 ml	per 1000 ml
Isoleucine	5.850 mg	2.925 g	5.850 g
Leucine	11.400 mg	5.700 g	11.400 g
Lysine monohydrate (equivalent to lysine)	8.930 mg (7.950 mg)	4.465 g (3.975 g)	8.930 g (7.950 g)
Methionine	5.700 mg	2.850 g	5.700 g
Phenylalanine	5.700 mg	2.850 g	5.700 g
Threonine	5.400 mg	2.700 g	5.400 g
Tryptophan	2.100 mg	1.050 g	2.100 g
Valine	7.200 mg	3.600 g	7.200 g
Arginine	16.050 mg	8.025 g	16.050 g
Histidine	5.250 mg	2.625 g	5.250 g
Alanine	22.350 mg	11.175 g	22.350 g
Glycine	19.200 mg	9.600 g	19.200 g
Aspartic acid	7.950 mg	3.975 g	7.950 g
Glutamic acid	16.200 mg	8.100 g	16.200 g
Proline	7.350 mg	3.675 g	7.350 g
Serine	3.000 mg	1.500 g	3.000 g
Tyrosine	0.500 mg	0.250 g	0.500 g
Acetylcysteine (equivalent to cysteine)	0.500 mg (0.370 mg)	0.250 g (0.185 g)	0.500 g (0.370 g)

### Electrolyte concentrations

Sodium	5.3 mmol/l
Total amino acids	150 g/l
Total nitrogen	24.0 g/l

### Excipient with known effect:

This medicinal product contains 5.3 mmol sodium per 1000 ml. To be taken into consideration in patients on a controlled sodium diet.

Excipients:

Sodium hydroxide

Citric acid monohydrate (for pH-adjustment)

Water for injections

### Pharmaceutical form

Solution for infusion

### Product Description

Clear, colourless up to faintly straw-coloured aqueous solution

Energy [kJ/l (kcal/l)] 2505 (600)

Theoretical osmolarity [mOsm/l] 1290

Acidity (titration to pH 7.4) [mmol NaOH/l] approx. 31

pH 5.7 – 6.3

### Indications

Supply of amino acids for parenteral nutrition, when oral or enteral nutrition is impossible, insufficient or contraindicated. For adults, adolescents and children over 2 years of age.

### Posology and method of administration

#### Posology

The dosage has to be 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 14 to 17 years*

#### Daily dose:

1.0 – 2.0 g amino acids/kg body weight

△ 6.7 – 13.3 ml/kg body weight

△ 469 – 931 ml for a 70 kg patient

#### Maximum infusion rate:

0.1 g amino acids/kg body weight/h △ 0.67 ml/kg body weight/h

△ 0.78 ml/min for a 70 kg patient

#### Paediatric population

*Newborn infants, infants and toddlers less than two years of age*

Aminoplasmal® 15% is contraindicated in newborn infants, infants and toddlers less than 2 years of age (see section "Contraindications").

*Children and adolescents 2 to 13 years*

The dosages for the age groups 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 children 2 to 4 years:

1.5 g amino acids/kg body weight △ 10 ml/kg body weight

#### Daily dose for children 5 to 13 years:

1.0 g amino acids/kg body weight △ 6.7 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).

#### Maximum infusion rate:

0.1 g amino acids/kg body weight/h △ 0.67 ml/kg body weight/h

In the case of amino acid requirements of 1.0 g/kg body weight/day or more, particular attention should be paid to the limitations of fluid input. To avoid fluid overload, amino acid solutions with higher amino acid content may have to be used in such situations.

#### Patients with renal/hepatic impairment

The doses should be adjusted individually in patients with hepatic or renal insufficiency (see also section "Special warnings and precautions for use"). Aminoplasmal® 15% is contraindicated in severe hepatic insufficiency and severe renal insufficiency in absence of renal replacement therapy (see section "Contraindications").

#### 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.

### Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed.
- 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

The medicinal product must not be administered to newborn infants, infants and toddlers less than two years of age, because the amino acid composition does not properly meet the special requirements of this paediatric age group.

### 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 "Contraindications". 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.

### Interaction with other medicinal products and other forms of interaction

None known.

### Fertility, pregnancy and lactation

#### Pregnancy

There are no or limited amount of data from the use of Aminoplasmal® 15% in pregnant women. The use of Aminoplasmal® 15% may be considered during pregnancy, if necessary.

#### Breastfeeding

Amino acids/metabolites are excreted in human milk, but at therapeutic doses of Aminoplasmal® 15% no effects on the breastfed newborn/infant are anticipated.

Nevertheless, breast-feeding is not recommended for mothers on parenteral nutrition.

#### Fertility

No data available.

### Effects on ability to drive and use machines

Not relevant.

### 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.

Such side effects can be allergic reactions, nausea and vomiting.

### 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 resumed later on at a lower infusion rate.

### Pharmacodynamic properties

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

ATC code: B05B A01

#### 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.

### 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.

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**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<sub>2</sub> or utilised as substrate for gluconeogenesis in the liver. The amino group is also metabolised in the liver to urea.

**Elimination**

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

**Preclinical safety data**

Non-clinical data available for the single components of the medicinal product reveal at common dosages no special hazard for humans based on conventional data of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

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

**Incompatibilities**

Aminoplasmal® 15% can only be mixed with other nutrients such as carbohydrates, lipids, vitamins and trace elements for which compatibility has been documented.

Compatibility data for different additives (e.g. electrolytes, trace elements, vitamins) and the corresponding shelf life of such admixtures can be provided on demand by the manufacturer. See also section "Special precautions for disposal and other handling".

**Shelf life**

*Unopened*  
3 years

**After first opening**

The medicinal product should be used immediately.

**After admixture of additives**

From a 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.

**Special precautions for storage**

Do not store above 30°C.

Do not freeze.

**Presentation**

Pack sizes: 500 ml

**Special precautions for disposal and other handling**

No special requirements for disposal.

Containers are for single use only. Discard container and any unused contents after use.

Only to be used if the solution is clear and colourless up to faintly straw-coloured and the bottle and its closure are undamaged.

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.

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Product registration holder:

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Sdn. Bhd.**

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