

**NAME OF THE MEDICINAL PRODUCT**

Aminoplasmal 15% Solution for Infusion

**COMPOSITION**

The solution for infusion contains

	<b>per 1 ml</b>	<b>per 500 ml</b>	<b>per 1000 ml</b>
Isoleucine	5.850 mg	2.925 g	5.850 g
Leucine	11.400 mg	5.700 g	11.400 g
Lysine monohydrate	8.930 mg	4.465 g	8.930 g
(equivalent to lysine)	(7.950 mg)	(3.975 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
Acetylcystein	0.500 mg	0.250 g	0.500 g
(equivalent to cysteine)	(0.370 mg)	(0.185 g)	(0.370 g)

1000ml of *solution* contain:

Electrolyte concentrations

Sodium 5.3 mmol/l

Total amino acids 150 g/l

Total nitrogen 24.0 g/l

*Excipients with known effect:*

This medicinal product contains 121.9 mg sodium per 1000 ml , equivalent to 6,095 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

**Excipients:**

Sodium hydroxide, citric acid monohydrate (for pH-adjustment), water for injections.

**THERAPEUTIC 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.

**CONTRAINDICATIONS**

Hypersensitivity to any of 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, hyperhydration, 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.

**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:

Uncommon: ( $\geq 1/1\ 000$  to  $< 1/100$ )

Not known: (cannot be estimated from the available data)

***Immune system disorders***

Not known: Allergic reactions

***Gastrointestinal disorders***

Uncommon: Nausea, vomiting

## **WARNINGS**

Keep out of the sight and reach of children.

For single use only. Discard unused contents. Do not re-connect partially used containers.

Use only if solution is clear, colourless up to faintly straw-coloured and the bottle and its closure are undamaged.

## **NOTE**

*Prescription only*

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

**B. Braun Melsungen AG, 34209 Melsungen, Germany, 11/2017**

Title: Aminoplasmal 15 % Initiator: Roxana ? Tranca

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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