

NAME OF THE MEDICINAL PRODUCT

Aminoplasma Hepa - 10 % Solution for Infusion

COMPOSITION

1000 ml of solution contain

Isoleucine	8.80 g
Leucine	13.60 g
Lysine acetate (equivalent to lysine)	10.60 g 7.51 g
Methionine	1.20 g
Phenylalanine	1.60 g
Threonine	4.60 g
Tryptophan	1.50 g
Valine	10.60 g
Arginine	8.80 g
Histidine	4.70 g
Glycine	6.30 g
Alanine	8.30 g
Proline	7.10 g
Aspartic acid	2.50 g
Asparagine monohydrate (equivalent to asparagine)	0.55 g 0.48 g
Acetylcysteine (equivalent to cysteine)	0.80 g 0.59 g
Glutamic acid	5.70 g
Ornithine hydrochloride (equivalent to ornithine)	1.66 g 1.30 g
Serine	3.70 g
N-Acetyltyrosine (Ph.Eur.) (equivalent to tyrosine)	0.86 g 0.70 g
<i>Electrolyte concentrations:</i>	
Acetate	51 mmol/l
Chloride	10 mmol/l
Total amino acids	100 g/l
Total nitrogen	15.3 g/l

Excipient with known effect: This medicinal product contains 0.3 to 2.3 mmol sodium per 1000 ml.

Excipients: Sodium hydroxide or hydrochloric acid (for pH adjustment), disodium edetate (Ph.Eur.), water for injection.

THERAPEUTIC INDICATIONS

Supply of amino acids as part of parenteral nutrition in patients with severe liver insufficiency with moderate to severe hepatic encephalopathy or acute or subacute liver failure.

For adults, adolescents and children over 2 years of age.

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 renal insufficiency in absence of renal replacement therapy, decompensated cardiac insufficiency, acute pulmonary edema, 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, since the amino acid composition does not properly meet the special requirements of this paediatric age group.

Based on the specific composition, Aminoplasma Hepa - 10 % may cause considerable metabolic disturbances if given outside the indications stated. Administration outside the specified therapeutic indication is contraindicated.

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 container and unused contents after use. Use only if solution is clear 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.

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