Aminoven infant 10%

Solution for infusion

Composition

1000 ml contains:

L-leucine	13.00 g
L-isoleucine	8.00 g
L-lysine acetate	12.00 g
= L-lysine 8.51 g	
L-methionine	3.12 g
L-phenylalanine	3.75 g
L-threonine	4.40 g
L-tryptophan	2.01 g
L-valine	9.00 g
Arginine	7.50 g
L-histidine	4.76 g
Glycine	4.15 g
L-taurine	0.40 g
L-serine	7.67 g
L-alanine	9.30 g
L-proline	9.71 g
N-acetyl-L-tyrosine	5.176 g
= L-tyrosine 4.20 g	
N-acetyl-L-cysteine	0.70 g
= L-cysteine 0.52 g	
L-malic acid	2.62 g
Total amino acids:	100 g/l
Total nitrogen content:	14.9 g/l
pH-value:	5.5 - 6.0

Other constituents: Water for injections

Theoretical osmolarity:

Address of the pharmaceutical company

885 mosm/l

Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H. Germany

Manufacturer

Fresenius Kabi Austria GmbH A-8055 Graz Austria

Indications

10% amino acid solution for partial parenteral nutrition, of infants (preterm and term newborns, babies) and

young children.

Together with corresponding amounts of electrolytes, carbohydrates, vitamins and fat emulsions as energy donors, the solution may serve for total parenteral nutrition.

Contraindications

Disturbances in amino acid metabolism, acidosis, hyperhydration, hypokalemia. Patients with insufficient renal or hepatic function require an individual dosage. Attention in case of hyponatremia.

Remark:

When administering amino acids as part of the parenteral nutrition of premature infants, babies and small children the following laboratory parameters must be regularly checked:

urea-N acid-base balance, serum ionogram, liver enzymes, lipid level (where fat emulsions are used), water balance and if necessary serum amino acids levels.

Posology and method of administrationFor constant intravenous infusion via

central veins.

Maximum infusion rate:

up to 0.1 g amino acids/kg body weight and hour = 1.0 ml/kg body weight/hour.

Maximum daily dosage:

- 1st year of living:
 - 1.5 2.5 g amino acids/kg body weight
- 2nd to 5th year of living:
 - 1.5 g amino acids/kg body weight
- 6th to 10th year of living:
 - 1.0 g amino acids/kg body weight
- 11th to 14th year of living:
 - 1.0 g amino acids/kg body weight

The solution is administered as long as parenteral nutrition is required.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section Precautions).

Remark:

Too rapid infusion may result in renal losses causing amino acid imbalance. Electrolytes should be administered according to the requirements.

Interactions with other medications

Because of the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other drugs.

Remark:

The addition of drugs may alter the chemical and physical properties of the solution and therefore give rise to toxic reactions.

Should it nevertheless become necessary to add drugs to Aminoven infant 10%, it is imperative to ensure sterility, complete mixing and compatibility. The same applies for the adding of lipid emulsions, trace elements and vitamins for complete parenteral nutrition mixtures.

Storage conditions

Store protected from light. Do not store above 25°C. When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section Precautions).

Precautions

Do not use Aminoven infant 10% after expiry date.

Use only clear solutions and undamaged containers.

Keep drugs out of the reach of children.

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 neonates and children below 2 years, Aminoven infant 10% should be protected from ambient light until administration is completed (see Posology and method of administration and Storage conditions).

Presentation

Available in 100 ml glass bottles packed in

cartons: 10 x 100 ml 10 x 250 ml

