APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

AMINOVEN INFANT 10 % Solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 000 ml contains:

Isoleucine	8,00 g
Leucine	13,00 g
Lysine acetate (= Lysine 8,51 g)	12,00 g
Methionine	3,12 g
Phenylalanine	3,75 g
Threonine	4,40 g
Tryptophan	2,01 g
Valine	9,00 g
Arginine	7,50 g
Histidine	4,76 g
Glycine	4,15 g
Alanine	9,30 g
Proline	9,71 g
Serine	7,67 g
Taurine	0,40 g
N-acetyl-L-tyrosine (= L-tyrosine 4,20 g)	5,176 g

N-acetyl-L-cysteine (= L-cysteine 0,52 g) 0,70 g

Malic acid 2,62 g

Total amino acids: 100,0 g/l

Total nitrogen: 14,9 g/l

Sugar free.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion

A clear solution in 100 ml, 250 ml and 1 000 ml glass bottles.

Titration acidity: 25 - 45 mmol NaOH/l

pH value: 5,5 – 6,0

Theoretical osmolarity: 885 mOsm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

AMINOVEN INFANT 10 % is a nitrogen source for partial parenteral nutrition therapy of infants (preterm and term newborns, babies) and young children when oral or enteral nutrition is impossible, insufficient or contraindicated. Together with required amounts of carbohydrates and fat as energy sources as well as vitamins, electrolytes and trace elements, the composite solution may serve for total parenteral nutrition.

4.2 Posology and method of administration

Posology

Maximum infusion rate:

Up to 0,1 g amino acids/kg body weight/hour = 1,0 ml/kg body weight/hour

Maximum daily dose:

- at the age of 1 year:

1,5 – 2,5 g amino acids/kg body weight = 15 – 25 ml per kg body weight

- at the age of 2 – 5 years:

1,5 g amino acids/kg body weight = 15 ml per kg body weight

- at the age of 6 – 14 years:

1,0 g amino acids/kg body weight = 10 ml per kg body weight

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

Method of administration

AMINOVEN INFANT 10 % should be administered as a constant intravenous infusion via a central vein.

AMINOVEN INFANT 10 % should be used with sterile transfer equipment immediately after opening. Any unused solution should be discarded.

Only clear, particle-free solutions in undamaged containers should be used.

For long-term parenteral nutrition with AMINOVEN INFANT 10 % essential fatty acids, vitamins and trace elements should be substituted.

4.3 Contraindications

The administration of AMINOVEN INFANT 10 % is contraindicated in the following conditions:

Disturbances of amino acid metabolism, inborn errors of amino acid metabolism, metabolic acidosis, hyperhydration and hyperkalaemia.

Patients with insufficient renal or hepatic function require an individual dosage.

Attention in case of hyponatraemia.

General contraindications to parenteral nutrition are unstable life-threatening circulatory conditions (shock), acid-base balance disturbances, insufficient cellular oxygen supply, hyperhydration, electrolyte disturbances, hyperlactataemia, and increased serum osmolarity, pulmonary oedema, decompensated cardiac insufficiency, and known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Frequent evaluation and determination of the following laboratory values should be recommended for monitoring parenteral nutrition in infants:

Urea-nitrogen, ammonia, electrolytes, glucose and triglycerides (when a fat emulsion is administered), acid-base and fluid balance, liver enzymes and serum osmolality.

Infusion via peripheral veins in general can cause irritation of the vein wall and thrombophlebitis. To minimise the risk of vein irritation, daily inspections of the insertion site are recommended.

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 sections 4.2, 6.3 and 6.6).

Special patient groups

Renal / hepatic impairment

See section 4.3.

Use in the elderly

No specific studies have been performed.

Effects on laboratory tests

No specific studies have been informed.

4.5 Interaction with other medicines and other forms of interaction

No interactions are known to date.

4.6 Fertility, pregnancy and lactation

Studies with this product have not been carried out on pregnant women. However, the clinical experience with similar parenteral amino acid solutions has not shown evidence of risk in pregnant and breastfeeding women.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

None known when correctly administered.

Vascular disorders:

Frequent: Thrombophlebitis and irritation of the cell wall especially when administered peripherally.

Gastrointestinal disorders:

Frequency unknown: Too rapid infusion may lead to nausea and vomiting.

Gastric hyperacidity, which should be treated with H_2 antagonists.

General disorders:

Frequency unknown: Too rapid infusion may lead to shivering attacks.

Renal losses with subsequent amino acid imbalances may occur if the infusion is too rapid.

Where the contraindications, precautions and dosage recommendations are adhered to, adverse reactions are unknown.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug

Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

As with other amino acid solutions shivering, vomiting, nausea and increased renal amino acid losses can occur when AMINOVEN INFANT 10 % is given in overdose or the infusion rate is exceeded. Infusion should be stopped immediately in this case. In the event of hyperkalaemia the infusion of 200 to 500 ml 10 % glucose solution with an added 1 to 3 U modified insulin / 3 - 5 g glucose is advisable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 23 Amino acids

Pharmacodynamic effects

The amino acids contained in AMINOVEN INFANT 10 % are all physiological compounds. As with the amino acids derived from the ingestion and assimilation of food proteins, parenterally administered amino acids enter the body pool of free amino acids and all subsequent metabolic pathways.

5.2 Pharmacokinetic properties

Absorption

The bioavailability of AMINOVEN INFANT 10 % is 100 %.

Distribution

The amino acids in AMINOVEN INFANT 10 % enter the plasma pool of corresponding free amino acids. Balanced amino acid solutions such as AMINOVEN INFANT 10 % do not

significantly alter the physiological amino acid pool when infused at a constant and slow infusion rate.

Biotransformation

The biological half-lives of amino acids in plasma depend on the age and metabolic situation of the paediatric patient.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

6.2 Incompatibilities

Because of the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other medicines. Should it become necessary to add other nutrients like carbohydrates, lipid emulsions, electrolytes, vitamins or trace elements to AMINOVEN INFANT 10 % for complete parenteral nutrition, aseptic admixing, good blending and, in particular, compatibility are absolute requirements.

6.3 Shelf life

24 months.

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 sections 4.2, 4.4 and 6.6).

6.4 Special precautions for storage

Store at or below 25 °C. Do not freeze.

Protect from light.

AMINOVEN INFANT 10 % should not be stored after addition of other components. Unless stability data is available, mixtures should be used within 24 hours.

6.5 Nature and contents of container

100 ml, 250 ml and 1 000 ml clear glass bottles, sealed with a rubber closure and an aluminium cap, packed in an outer carton in the following package sizes:

10 x 100 ml

10 x 250 ml

1 x 1 000 ml

10 x 1 000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

When used in neonates and children below 2 years, protect from light exposure, until administration is completed. Exposure of AMINOVEN INFANT 10 % 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).

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Fresenius Kabi South Africa (Pty) Ltd

Stand 7

Growthpoint Business Park

162 Tonetti Street

Halfway House, Midrand, 1685

South Africa

8. REGISTRATION NUMBER

A39/23/0182

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 December 2006

10. DATE OF REVISION OF THE TEXT

19 October 2022