Applicant: Fresenius Kabi South Africa (Pty) Ltd.
Product Name: Aminosteril N-Hepa 8
Dosage form and strength: Solution for infusion; Multicomponent

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S3

1 NAME OF THE MEDICINE

AMINOSTERIL N-HEPA 8 % (Solution for Infusion)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains per 1 litre of the solution:

Total amino acid content:

L-Isoleucine	10,40 g
L-Leucine	13,09 g
L-Lysine monoacetate	9,71 g
corresponding to L-Lysine	6,88 g
L-Methionine	1,10 g
N-acetyl-L-cysteine	0,70 g
corresponding to L-Cysteine	0,52 g
L-Phenylalanine	0,88 g
L-Threonine	4,40 g
L-Tryptophan	0,70 g
L-Valine	10,08 g
L-Arginine	10,72 g
L-Histidine	2,80 g
Aminoacetic acid (glycine)	5,82 g
L-Alanine	4,64 g
L-Proline	5,73 g
L-Serine	2,24 g
Acetic acid	4,42 g

Sugar-free.

For full list of excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Product is a clear, colourless to light yellow solution~~s~~, practically free from visible particles.

pH: 5.7 – 6.3

Osmolarity: 770 mOsm/L

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

AMINOSTERIL N-HEPA 8 % is indicated as a source of amino acids as part of total parenteral nutrition regimens to provide protein in patients with hepatic insufficiencies.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

The recommended dosage is 1,0 to 1,25 mL/kg body weight/hour = 0,08 – 0,1 g amino acids per kg body weight and hour.

Maximum infusion rate

1,25 mL/kg body weight/hour corresponding to 0,1 g amino acids/kg body weight/hour.

Maximum daily dose

1,5 g amino acids/kg body weight corresponding to 18,75 mL/kg body weight corresponding to 1 300 mL at 70 kg body weight.

AMINOSTERIL N-HEPA 8 % is applicable as part of total parenteral nutrition regimen in combination with adequate amounts of energy supplements (carbohydrate solutions, fat emulsions), electrolytes, vitamins and trace elements.

For an optimal administration, carbohydrate solutions and/or fat emulsions should be given simultaneously.

The preparation may be used for as long as required by the patient‘s clinical condition or until the amino acid metabolism of the patient has normalised.

Paediatric population

There is no experience in children.

Method of administration

For intravenous infusion only.

For administration via a peripheral or central vein

See section 6.6 for Special Precautions for Disposal and Handling.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients listed in section 2 or to any of the excipients listed in section 6.1.
- Disturbed amino acid metabolism, metabolic acidosis, fluid overload, hyperhydration conditions, hyponatraemia, hypokalaemia, hyperkalaemia, renal insufficiency, serious cardiac function disorders, shock and hypoxia.
- Safety during pregnancy and in children has not been established.

4.4 Special warnings and precautions for use

It is necessary to monitor serum electrolytes, the water balance and the acid-base status. Laboratory monitoring should also include blood glucose, serum protein, creatinine, and liver function tests.

Electrolytes and energy sources should be added in balanced portions, and infused, as necessary, using a bypass or mixed in an All-in-One bag.

Due to the special composition of this preparation, use in indications other than those recommended may result in amino acid imbalances and severe metabolic disorders.

The choice of a peripheral or central vein depends on the final osmolarity of the mixture. The general accepted limit for peripheral infusions is about 800 mosm/L, but it varies considerably with the age and the general condition of the patient and the characteristics of the peripheral veins.

In order to minimise the risk of thrombophlebitis while using a peripheral application, frequent checks of the infusion site are recommended.

4.5 Interactions with other medicines and other forms of interaction

No interactions are known to date.

Please refer to section 6.2 “Incompatibilities”.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established (see section 4.3).

4.7 Effects on ability to drive and use machines

AMINOSTERIL N-HEPA 8 % has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Thrombophlebitis may occur if peripheral veins are used.

No other undesirable effects are known when the solution is correctly administered.

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via Med Safety APP (Medsafety X SAHPRA) or via the eReporting platform (who-umc.org) found on the SAHPRA website.

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine’s regulatory authority in the country where the product is marketed.

4.9 Overdose

AMINOSTERIL N-HEPA 8 % is an amino acid solution for parenteral nutrition. Acute intoxication is unlikely if the solution is used as recommended.

A too rapid infusion via peripheral veins can cause thrombophlebitis (osmolarity of the solution).

Depending on the extent of any pre-existing, pathologically-induced dysregulation and impairment of hepatic capacity, nausea, vomiting, chills and renal amino acid losses may occur in some patients after overdosage.

If symptoms of overdose occur, the infusion should be slowed down or discontinued.

The treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 25.2 Other nutrients

Pharmacotherapeutic group: amino acids - solution for parenteral nutrition, ATC code: B05BA01

The following is characteristic of patients with hepatic insufficiency:

- An increase in plasma ammonia concentrations
- Severe imbalances in the plasma amino acid profile, whereby concentrations of the branched chain amino acids (valine, leucine, isoleucine) are reduced and concentrations of the aromatic amino acids (tyrosine, phenylalanine, tryptophan) and of methionine are elevated
- Hypercatabolism

These factors in combination, and the resultant cerebral alterations, are postulated to be mainly responsible for the development of hepatic encephalopathy and hepatic coma.

In order to normalise the factors above within the framework of infusion therapy, it has been found to be of benefit if amino acid infusion solutions are administered which contain:

a) A high proportion of branched-chain amino acids

b) At the same time a low proportion of aromatic amino acids and methionine

The amino acids, constituents of protein in ordinary food, are utilised for tissue protein synthesis and any surplus is channelled to a number of metabolic pathways. Studies have shown thermogenic effect of amino acid infusion.

AMINOSTERIL N-HEPA 8 % is L-amino acid solution formulated with a small percentage of methionine, phenylalanine and tryptophan and an increased proportion of the branched-chain amino acids (BCAAs) leucine, isoleucine and valine. The product contains 42 % of BCAAs. It has a positive influence on the nitrogen balance and prevents a further increase in the ammonia level.

5.2 PHARMACOKINETIC PROPERTIES

AMINOSTERIL N-HEPA 8 % is given by intravenous administration as part of a parenteral nutritional regimen, and thus has a bioavailability of 100 %.

The composition of AMINOSTERIL N-HEPA 8 % takes into account the impairment of amino acid metabolism accompanying severe hepatic insufficiency.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

6.2 Incompatibilities

Amino acid solutions should not be mixed with other medicines, except for parenteral nutrition products, due to the risk of microbiological contamination and incompatibilities.

6.3 Shelf life

Shelf-life of the unopened product:

3 years

Shelf-life after first opening:

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately.

Shelf-life after mixing with other components:

AMINOSTERIL N-HEPA 8 % may be used in total parenteral nutrition (TPN) admixtures.

From a microbiological point of view the product should be used immediately. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user. Normally, the admixture should not be stored longer than 24 hours at 2 to 8 ^{o}C, unless admixing has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light.

6.5 Nature and contents of container

500 mL hydrolytic resistance type II, colourless, glass infusion bottles with halobutyl rubber stopper and flip-off cap.

Pack size: 10's

6.6 Special precautions for disposal and other handling

For intravenous use only.

To be used immediately after the bottle is opened.

AMINOSTERIL N-HEPA 8 % should be used only with sterile transfer equipment.

For single use only.

Do not use AMINOSTERIL N-HEPA 8 % after expiry date.

Use only clear, particle-free solutions and undamaged containers.

Discard unused solutions. Any admixture remaining after infusion must be discarded.

Amino acid solutions should not be mixed with other medicines, except for parenteral nutrition products, due to the increased risk of microbiological contamination and incompatibilities.

When mixing with other nutrients like carbohydrates, lipid emulsions, electrolytes, vitamins or trace elements to AMINOSTERIL N-HEPA 8 % for complete parenteral nutrition, care should be given to aseptic techniques, thorough mixing and, in particular, to compatibility.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

AMINOSTERIL N-HEPA 8 %: Y/25.2/370

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 May 1993

10 DATE OF REVISION OF THE TEXT

24 December 2025

Namibia NS2
04/25.5/1035, POM
Kenya 7430, POM