SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Nephrosteril

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml solution of infusion contain:

L-Isoleucine……5.10g

L-Leucine……10.30g

L-Lysine monoacetate……10.01g

L-Methionine……2.80g

N-Acetyl-L-Cysteine……0.50g

L-Phenylalanine……3.80g

L-Threonine……4.80g

L-Tryptophan……1.90g

L-Valine……6.20g

L-Arginine……4.90g

L-Histidine……4.30g

Glycine……3.20g

L-Alanine……6.30g

L-Proline…….4.30g

L-Serine……4.50g

L-Malic acid……1.50g

Glacial acetic acid……1.38

Total amino acids……70.0 g/l

Total nitrogen……10.8 g/l

Total energy……1210 kJ/l (= 280 kcal/l)

Theoretical osmolarity……645 mosm/l

3. PHARMACEUTICAL FORM

Solution for infusion.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Balanced supply of protein elements in acute and chronic renal insufficiency as well as during peritoneal and hemodialysis treatment.

4.2 Posology and method of administration

For intravenoues infusion.

If not otherwise prescribed up to 0.5 g amino acids / kg BW and day (= 500 ml per day at 70 kg body weight in acute and chronic renal insufficiency **without** dialysis treatment. Up to 1.0 g amino acids / kg BW and day (= 1000 ml per day at 70 kg body weight) in acute and chronic renal insufficiency **under** dialysis treatment.

Max. dosage:
Up to 1.5 g amino acids / kg BW and day (= 1500 ml per day at 70 kg body weight). The drop rate should not exceed 20 drops/minute.
Administer calory carriers either before or simultaneously by mouth or parenterally.

Duration of application:
In acute renal insufficiency duration of application is from some days up to maximum of two weeks.
In chronic renal insufficiency **without** dialysis treatment as well as in acute and chronic renal insufficiency **under** dialysis hemodialysis, hemofiltration, or

peritoneal dialysis treatment Nephrosteril can be used until a sufficient **oral** supply of protein can be again given.

4.3 Contraindications

Impaired amino acid metabolism, advanced functional impairment of the liver, severe cardiac insufficiency, hyperhydration, hypokalemia, hyponatremia.

4.4 Special warnings and precautions for use

This solution does not contain electrolytes, observe therefore the blood electrolyte level.

If necessary, supply sufficient potassium in order to ensure the anabolic utilitzation of amino acids. Monitor regularly the water-electrolyte metabolism as well as the acid-base status and serum urea. A possibly existing reduction of renal function has to be treated at first by supplying sufficient amounts of water and electrolytes.

The infusion of Nephrosteril may lead to increased production of gastric acid and stress ulcer.

4.5 Interaction with other medicinal products and other forms of interaction

The addition of drugs should be avoided, as additives may lead to chemico-physical changes in the amino acid solution and thus to toxic reactions. If drugs have to be given, observe sterility, complete mixture, changes in the solution and general compatibility.

Solutions with drugs must not be stored.

4.6 Fertility, pregnancy and lactation

Studies with this product have not been carried out on pregnant and breastfeeding women.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

None known

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via Pharmacy and the Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Side effects

Excessive drop rates may lead to incompatibility such as nausea, chills, and vomiting.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B05B A01 - amino acids - solution for parenteral nutrition

The amino acids contained in **Aminoven 10%** are all naturally occuring 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

Nephrosteril is administered by the intravenous route and, therefore, is 100% bioavailable.

5.3 Preclinical safety data

Provided the recommended dosing regimen is complied with, toxic reactions to Nephrosteril are not known and are not to be expected.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store protected from light and not above 25°C!

6.5 Nature and contents of container

Glass bottles, 250 ml and 500 ml
Type II, colourless glass, rubber closure/aluminium cap and outer carton.

Package sizes: 10 x 250 ml glass bottle
10 x 500 ml glass bottle

6.6 Instructions for use/handling

Do not use Nephrosteril after expiry date!
Do not used if the solution is cloudy or if the container is

damaged. Keep out of the reach of children.

7. MARKETING AUTHORISATION HOLDER

Fresenius Kabi South Africa (Pty) Limited
Stand 7, Growthpoint Business Park, 162
Tonetti Street, Halfway House Extension 7
Midrand, South Africa.

8. MARKETING AUTHORISATION NUMBER

CTD7124

9. DATE OF FIRST AUTHORISATION

22/01/2026

10. DATE OF REVISION OF THE TEXT

24/02/2026