SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

RENOSAN®

Amino Acid 500 mL, Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 500 mL contains:

L-Threonine	2.25 g
L-Serine	2.5 g
L-Proline	4.0 g
L-Cysteine HCl.H_2O	0.2 g
Glycine	4.5 g
L-Alanine	3.75 g
L-Valine	4.2 g
L-Methionine	0.5 g
L-Isoleucine	4.5 g
L-Leucine	5.5 g
L-Phenylalanine	0.5 g
L-Tryptophan	0.35 g
L-Histidine HCl.H_2O	1.6 g
L-Lysine HCl	3.8 g
L-Arginine HCl	3.65 g

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

The solution is clear, colorless to yellowish, with a characteristic odor.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of hepatic encelophalophaty in patients with chronic liver disease.

4.2 Posology and Method of Administration

Route of administration: Intravenous

Adults

500 – 1000 mL/dose by intravenous infusion.

Peripheral Infusion Rate: 500 mL over 180 – 300 min (approximately 25 – 40 drops/min) in adults.

Total Parenteral Nutrition

500 – 1000 mL of **RENOSAN®** should be suitable combined with dextrose/glucose or other solutions and administered over 24 hours via the central vein. The dosage may be adjusted depending on the patient's age, symptoms, and body weight.

4.3 Contraindications

- Patients with severe renal disorder.
- Patients with abnormal amino acid metabolism (since the infused amino acids are not adequately metabolized, the patient's clinical condition may be worsened).

4.4 Special Warnings and Precaution for Use

- Careful administration in patients with severe acidosis and congestive heart failure.
- Use with electrolyte solution and administration of the solution in large doses require careful supervision of electrolyte balance.
- The safety of **RENOSAN®** in prematures, newborns and suckling babies, and children has not been established.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

No interaction studies have been performed.

4.6 Fertility, Pregnancy, and Lactation

There are no adequate data regarding the effects of **RENOSAN®** on fertility, or its use in pregnant or lactating women.

4.7 Effects on Ability to Drive and Use Machines

There is no information of the effects of **RENOSAN®** on the ability to operate a vehicle or other heavy machinery.

4.8 Undesirable Effects

- Hypersensitivity
  Skin rashes or other hypersensitive reactions have been rarely reported, administration should be discontinued if such signs developed.
- Digestive
  Nausea and vomiting may infrequently occur.
- Cardiovaskular
  Chest discomfort and palpitations may infrequently occur.
- Large dose and rapid administration:
  Acidosis may occur after a rapid and large dose of **RENOSAN®**.
- Main adverse reaction
  Hypoglycemia and hyperammonemia.
- Metabolic
  The nitrogen content of this preparation may induce a transient increase in blood ammonia concentrations.
- Others
  Fever, chills, headache, and vascular pains.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via National vigilance systems.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance

of the medicinal product. Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org '

4.9 Overdose

In the event of inappropriate administration (overdose, and/or infusion rate higher than recommended), hypervolemia, electrolyte disturbances, acidosis and/or azotemia may occur. In such situations, the infusion must be stopped immediately. If medically appropriate, further intervention may be indicated to prevent clinical complications.

There is no specific antidote for overdose. Emergency procedures should include appropriate corrective measures.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group : Amino Acids/Carbohydrates/Minerals/Vitamins, Combinations ATC Code : V06DE

Mechanism of Action

RENOSAN® normalized the pattern of free amino acids in the plasma and brain, improved serotonin metabolism in the brain and corrected a sleep-wakefulness in a rat model of chronic hepatic insufficiency which underwent a portacaval shunt operation. When infused to portacaval-shunted rats loaded with ammonia, **RENOSAN®** improved EEG pattern and corrected amine metabolism in the brain, after infusion to portacaval-shunted rats loaded with ammonia.

5.2 Pharmacokinetic Properties

None stated.

5.3 Preclinic Safety Data

No data is presented as amino acids are basic and widespread elements in mammalian metabolism. Therefore conventional animal safety testing is not appropriate.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium
Metabisulfite
Sodium
Hydroxide Water
for Injection

6.2 Incompatibilities

Additives may be incompatible.
Do not add other medicinal products or substances without first confirming their compatibility and the stability of the resulting preparation.
Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store below 30°C, away from light.

6.5 Nature and Contents of the Container

Each bottle of **RENOSAN®** contains Amino Acids and is filled in a 500 mL Type II clear glass bottle, closed with a 32 mm rubber stopper and sealed with a 32 mm flip-off cap.
Each box contains with 1 bottle @ 500 mL.

6.6 Special Precautions for Disposal and Other Handling

No special requirements for disposal.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

7.1 Marketing Authorization Holder

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8. MARKETING AUTHORIZATION NUMBER

H2010/20063/320

9. DATE OF FIRST REGISTRATION

26/06/2026

10. DATE OF REVISION OF THE TEXT

26/06/2026