PROFESSIONAL INFORMATION

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

GLAMIN solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 500 mL of GLAMIN solution contains:

Amino acids:

L-alanine	8,00 g
L-arginine	5,65 g
L-aspartic acid	1,70 g
L-glutamic acid	2,80 g
Glycyl-glutamine H_2O	15,14 g
(corresponding to glycine 5,14 g	
and glutamine 10,00 g)	
Glycyl-tyrosine $2H_2O$	1,73 g
(corresponding to glycine 0,47 g	
and tyrosine 1,14 g)	
L-histidine	3,40 g
L-isoleucine	2,80 g
L-leucine	3,95 g
L-lysine acetate	6,35 g
(corresponding to L-lysine 4,50 g)	
L-methionine	2,80 g

L-phenylalanine	2,93 g
L-proline	3,40 g
L-serine	2,25 g
L-threonine	2,80 g
L-tryptophan	0,95 g
L-valine	3,65 g

500 mL of GLAMIN solution contains 67 g total amino acids corresponding to 11,2 g total nitrogen.

Energy content: 1 150 kJ (270 kcal)/500 mL

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.

Clear, colourless to slightly yellow solution.

Theoretical osmolarity: 1 040 mOsm/L

pH: 5,8

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GLAMIN provides amino acids as part of parenteral nutrition therapy when oral or enteral nutrition is impossible, insufficient or contraindicated.

In parenteral nutrition regimens, amino acid solutions should always be administered in combination with appropriate energy-supplying infusion solutions.

4.2 Posology and method of administration

Posology

In order to ensure optimal utilisation of the infused amino acids and dipeptides, the patient's requirements of energy (carbohydrates, fat), electrolytes, trace elements and vitamins should be covered.

Recommended dosage for adults

The dosage depends on the amino acid requirements.

Generally, 1 – 1,4 g amino acids/dipeptides (corresponding to 0,17 – 0,23 g nitrogen) per kg body weight per day is recommended. This corresponds to 7 – 11 mL GLAMIN/kg body weight/day or to 500 – 750 mL GLAMIN/day for a patient weighing 70 kg.

Recommended infusion rate: 0,45 – 0,50 mL (corresponding to 0,06 –0,07 g amino acids/dipeptides)/kg body weight/hour. This corresponds to 375 mL in 10 – 12 hours or 750 mL in 20 – 24 hours for patients weighing 70 kg.

Paediatric population

GLAMIN is not indicated for use in children.

Method of administration

Intravenous infusion. GLAMIN should be administered by the central venous route due to its high osmolarity (above 800 mOsm/L). For single use only.

Most of the clinical experience so far is limited to 7 days of GLAMIN administration. No experience is available to date regarding administration for more than 2 weeks.

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.

- Patients with inborn errors of amino acid metabolism, impairment of liver function and severe impairment of renal function.
- General contraindications to parenteral nutrition are:
    - unstable life-threatening circulatory conditions (shock),
    - metabolic acidosis,
    - insufficient cellular oxygen supply,
    - over-hydration,
    - electrolyte disturbances,
    - hyperlactataemia,
    - increased serum osmolarity,
    - pulmonary oedema,
    - decompensated cardiac failure.
- The safety in pregnancy and lactation has not been established (see section 4.6).
- GLAMIN is not indicated for use in children (see section 4.2).

4.4 Special warnings and precautions for use

The solution is hypertonic and thrombophlebitis may occur when the solution is infused into peripheral veins.

Monitoring advice:

Serum electrolytes, serum osmolarity, water balance, acid-base status as well as liver function tests (alkaline phosphatase, ALT, AST) should be monitored.

Paediatric population

GLAMIN is not indicated for use in children (see sections 4.2 and 4.3).

4.5 Interaction with other medicines and other forms of interaction

Amino acid solutions should not be used as carrier solutions for medicines.

GLAMIN may only be mixed with other solutions where compatibility is documented (see section 6.6).

4.6 Fertility, pregnancy and lactation

Pregnancy and breastfeeding

The safety in pregnancy and lactation has not been established.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

General disorders:

The following side effects have been reported and the frequencies are unknown:

When infusion rates exceed the recommended maximum rate, signs of intolerance may occur: nausea, vomiting, flushing and sweating in combination with renal excretion of amino acids and dipeptides.

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 requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and 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 medicines' regulatory authority in the country where the product is marketed.

4.9 Overdose

See section 4.8 above. If symptoms of overdosage occur, reduce infusion rate, or, if necessary, stop the infusion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 25.2 Other nutrients

ATC code: B05BA01

Mechanism of action:

This amino acid solution is a source of amino acids for metabolism.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid (for pH-adjustment)

Water for injection

6.2 Incompatibilities

This medicine must not be mixed with other medicines except those mentioned in section 6.6.

6.3 Shelf life

18 months.

GLAMIN should be used immediately after opening of the bottle.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Glass bottle containing 500 mL of solution.

Packed as 10 x 500 mL into cartons.

6.6 Special precautions for disposal and other handling

Use only clear solutions in intact containers.

Compatibility

The following may be mixed with 750 mL GLAMIN: up to 750 mL Intralipid 20 %, 750 mL glucose 40 % solution, 60 mmol NaCl, 3,75 mmol $CaCl_2$, 45 mmol KCl, 2,6 mmol Mg-L-hydrogen-glutamate, trace elements, water-soluble and fat-soluble elements.

Additions should be performed aseptically immediately before the start of the infusion. Discard any unused contents.

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

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

31/25.2/0087

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

12 March 1999

10. DATE OF REVISION OF THE TEXT

16 October 2025

Namibia	NS2	04/25.2/0329