**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S3**

# GLAMIN solution for infusion

## Sugar free

**Read all of this leaflet carefully before you are given GLAMIN**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

**What is in this leaflet**


1. What GLAMIN is and what it is used for
2. What you need to know before you are given GLAMIN
3. How GLAMIN will be administered to you
4. Possible side effects
5. How to store GLAMIN
6. Contents of the pack and other information


## 1. What GLAMIN is and what it is used for

GLAMIN is a solution which contains amino acids. It is used in patients who are unable to take in food by mouth or cannot have tube feeding, or when these routes are contraindicated or do not provide enough nutrients to the body. GLAMIN is given by infusion directly into a vein (parenteral feeding).

## 2. What you need to know before you are given GLAMIN

**GLAMIN should not be administered to you:**

- if you are hypersensitive (allergic) to any of the active substances or to any of the other ingredients of GLAMIN (listed in section 6)
- if your body cannot break down amino acids
- if you have problems with your liver
- if you have severe kidney problems
- if you have a condition where you may not receive parenteral feeding (e.g. shock, a pH imbalance in your body, too little oxygen supply to your body's tissues, excess water content in your body, salt disturbances, fluid in your lungs, heart failure)
- the safety of the use of GLAMIN in pregnancy and breastfeeding has not been established (see "Pregnancy and breastfeeding")
- GLAMIN must not be used in children.

**Warnings and precautions**

Tell your doctor or healthcare provider before being given the injection:

**Take special care with GLAMIN:**

- Inflammation of the vein with the formation of a blood clot may occur when the solution is given into one of your veins in your arms, hands, legs or feet.
- Your doctor or a healthcare provider will monitor the following while you are receiving GLAMIN:
  - salts and minerals in your blood
  - water balance
  - acid-base status
  - liver function.

**Children**

GLAMIN must not be used in children (see "GLAMIN should not be administered to you").

**Other medicines and GLAMIN**

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Amino acid solutions such as GLAMIN should not be used as carrier solutions for medicines. GLAMIN should only be mixed with solutions that have been proven to be compatible.

**Pregnancy and breastfeeding**

The safety of the use of GLAMIN in pregnancy and breastfeeding has not been established.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before receiving GLAMIN.

**Driving and using machines**

It is not always possible to predict to what extent GLAMIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GLAMIN affects them.

## 3. How GLAMIN will be administered to you

You will not be expected to give yourself GLAMIN. It will be given to you by a person who is qualified to do so.
Your doctor will decide the exact amount that you should receive. The amount that you receive will depend on your body's needs for amino acids.
GLAMIN is given by infusion directly into a vein.

**If you receive more GLAMIN than you should**

Since a healthcare provider will administer GLAMIN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**If you forget to receive GLAMIN**

Since a healthcare provider will administer GLAMIN, it is unlikely that the dose will be missed.

## 4. Possible side effects

GLAMIN can have side effects:

- nausea and vomiting
- flushing and sweating
- amino acids and its breakdown products may be excreted by the kidneys.

Not all side effects reported for GLAMIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving GLAMIN, please consult your healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of GLAMIN.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or 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.

## 5. How to store GLAMIN

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use this medicine after the expiry date stated on the bottle.

Use immediately after opening the bottle. Discard any unused contents.

Use only clear solutions in intact containers.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What GLAMIN contains

The active substances in each 500 mL of GLAMIN solution are:

**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 |

The other ingredients are:

Citric acid (for pH-adjustment)

Water for injection

Sugar free.

**What GLAMIN looks like and contents of the pack**

GLAMIN is a clear, colourless to slightly yellow solution.

Glass bottle containing 500 mL of solution.

Packed as 10 x 500 mL into cartons.

**Holder of Certificate of Registration**

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**Access to the corresponding Professional Information**

The corresponding Professional Information (PI) can be accessed at https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products