

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

AMINOVEN 5 % Solution for infusion

AMINOVEN 10 % Solution for infusion

AMINOVEN 15 % Solution for infusion

Strength: 5 %, 10 %, 15 % (multicomponent amino acids)

Sugar free.

Read all of this leaflet carefully before you are given AMINOVEN 5 %, 10 % or 15 % solution for infusion.

- 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 AMINOVEN 5 %, 10 % or 15 % is and what it is used for
2. What you need to know before you receive AMINOVEN 5 %, 10 % or 15 %
3. How to receive AMINOVEN 5 %, 10 % or 15 %
4. Possible side effects
5. How to store AMINOVEN 5 %, 10 % or 15 %
6. Contents of the pack and other information

1. What AMINOVEN 5 %, 10 % or 15 % is and what it is used for

AMINOVEN 5 %, 10 % or 15 % provides nourishment straight into your blood stream when you cannot eat normally. It provides amino acids which your body will use to make proteins

(to build and repair muscles, organs, and other body structures).

AMINOVEN 5 %, 10 % and 15 % are administered through an injection into a vein when oral supply of amino acids is not possible, not enough or not allowed due to a medical condition.

2. What you need to know before you receive AMINOVEN 5 %, 10 % or 15 %

AMINOVEN 5 %, 10 % or 15 % should not be administered to you:

- If you are hypersensitive (allergic) to any of the ingredients in AMINOVEN 5 %, 10 % or 15 %.
- If you have a condition which causes a low oxygen supply to your body (hypoxia).
- If your doctor confirms that you have disturbances in sodium, potassium or amino acid concentrations in your body.
- If you have a liver or kidney disorder and are not on dialysis or another form of blood filtration treatment.
- If you have high blood sugar and you require 6 or more units of insulin per hour.
- If you have a heart disorder (decompensated heart failure).
- If you have an excessive amount of fluids in your body (a condition called overhydration).
- If you have a condition where your body has problems using proteins or amino acids.
- If you have metabolic acidosis (the acid levels of your body fluids and tissues become too high).
- If you suffer from shock.

Your child should not receive AMINOVEN 5 % and 10 % if your child is younger than 2 years of age.

Your child should not receive AMINOVEN 15 %.

Warnings and precautions

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

- If you have a heart disorder (cardiac insufficiency) and the doctor need to infuse a large volume of fluids.
- If your doctor prescribes amino acid solutions daily, as folic acid deficiency may develop. Your doctor may need to prescribe a folic acid supplement daily as well.
- If you suffer from low levels of potassium (hypokalaemia).
- If you suffer from low levels of sodium (hyponatraemia).

Your doctor may need to draw blood regularly to monitor you or your child's electrolyte and blood sugar levels. Your doctor may also need to test you or your child's kidney function regularly.

Other medicines and AMINOVEN 5 %, 10 % or 15 %

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

No interactions with other medicines are known.

AMINOVEN 5 %, 10 % and 15 % should not be mixed with other medicines.

AMINOVEN 5 %, 10 % or 15 % with food and drink and alcohol

Not Applicable

Pregnancy, breastfeeding and fertility

Safety of AMINOVEN 5 %, 10 % and 15 % during 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 AMINOVEN 5 %, 10 % or 15 %.

Driving and using machines

It is not always possible to predict to what extent AMINOVEN 5 %, 10 % or 15 % 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 AMINOVEN 5 %, 10 % or 15 % affects them.

3. How to receive AMINOVEN 5 %, 10 % or 15 %

You will not be expected to give yourself AMINOVEN 5 %, 10 % or 15 %. It will be given to you by a person who is qualified to do so.

You will receive your medicine by infusion (IV drip).

AMINOVEN 5 %, 10 % and 15 % will only be administered through a vein in a hospital.

The amount and rate at which the infusion is given depends on your requirements.

AMINOVEN 15 % is not intended for children. See section 2.

Your doctor will decide on the correct dose for you or child and how long your treatment or your child's treatment will be.

You may be monitored during your treatment.

If you receive more AMINOVEN 5 %, 10 % or 15 % than you should

Since a healthcare provider will administer AMINOVEN 5 %, 10 % or 15 %, he/she will control the dosage. However, in the event of overdosage, your doctor/ your child's doctor will manage the overdosage. The effects of an overdose may include nausea, vomiting and shivering.

If you forget to take AMINOVEN 5 %, 10 % or 15 %

Since a healthcare provider will administer AMINOVEN 5 %, 10 % or 15 %, it is unlikely that the dose will be missed.

4. Possible side effects

AMINOVEN 5 %, 10 % and 15 % may have side effects.

Not all side effects reported for AMINOVEN 5 %, 10 % and 15 % are included in this leaflet.

Should your, or your child's general health worsen or if you experience any untoward effects while receiving AMINOVEN 5 %, 10 % and 15 %, please consult your healthcare provider for advice.

Side effects you may experience include:

- Nausea and vomiting
- Pain and irritation where AMINOVEN 5 %, 10 % and 15 % is injected into your body.

The following side effects have been observed when infusion was administered too quickly:

- loss of potassium or sodium from the blood
- folate deficiency

At the site of injection the following side effects may occur:

- soreness and tenderness of the vein
- thrombosis (the formation of a clot) in the vein where the injection is given

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of AMINOVEN 5 %, 10 % or 15 %.

5. How to store AMINOVEN 5 %, 10 % or 15 %

- Store at or below 25 °C.
- Do not freeze.
- Keep container in the outer carton.
- Store all medicines out of reach of children.
- Do not use AMINOVEN 5 %, 10 % or 15 % after the expiry date.
- Return all unused medicine to the pharmacy for disposal.

6. Contents of the pack and other information

What AMINOVEN 5 %, 10 % or 15 % contains

Each 1 000 ml contains: various amino acids

Active ingredients	Quantity (g)		
	AMINOVEN 5 %	AMINOVEN 10 %	AMINOVEN 15 %
Isoleucine	2,50	5,00	5,20
Leucine	3,70	7,40	8,90
Lysine acetate	4,655	9,31	15,66
Methionine	2,15	4,30	3,80
Phenylalanine	2,55	5,10	5,50
Threonine	2,20	4,40	8,60
Tryptophan	1,00	2,00	1,60
Valine	3,10	6,20	5,50
Arginine	6,00	12,00	20,00
Histidine	1,50	3,00	7,30
Alanine	7,00	14,00	25,00
Glycine	5,50	11,00	18,50
Proline	5,60	11,20	17,00
Serine	3,25	6,50	9,60
Tyrosine	0,20	0,40	0,40
Taurine	0,50	1,00	2,00

Other ingredients:

Glacial acetic acid (for pH-adjustment), water for injection

In addition in AMINOVEN 15 % only: Malic acid (for pH-adjustment)

What AMINOVEN 5 %, 10 % or 15 % looks like and contents of the pack

AMINOVEN 5 % and 10 %: A clear solution in 500 ml and 1 000 ml glass bottles.

AMINOVEN 15 %: A clear solution in 250 ml, 500 ml and 1 000 ml glass bottles

AMINOVEN 5 % and 10 %:

500 ml and 1 000 ml clear glass bottles, sealed with a rubber closure and an aluminium cap, packed in an outer carton in the following package sizes:

1 x 500 ml

10 x 500 ml

1 x 1000 ml

6 x 1 000 ml

AMINOVEN 15 %:

250 ml, 500 ml and 1 000 ml clear glass bottles, sealed with a rubber closure and an aluminium cap, packed in an outer carton in the following package sizes:

10 x 250 ml

10 x 500 ml

6 x 1 000 ml

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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