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● Schwarz

Glycine	3.85
Proline	3.92
Serine	2.275
Taurine	0.35
Glucose monohydrate	55.0 (correspond to 50.0 g anhydrous Glucose)
Sodium chloride	1.169
Calcium chloride dihydrate	0.294
Magnesium chloride hexahydrate	0.61
Zinc chloride	0.00545
Sodium glycerophosphate hydrated	4.592
Potassium hydroxide	1.98

Aminoven 3.5% also contain acetylcysteine, malic acid and water for injections.

What Aminoven 3.5% looks like and contents of the pack

Aminoven 3.5% is supplied in sealed glass bottles which contain either 500 ml or 1000 ml of the solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fresenius Kabi Limited
Cestrian Court,
Eastgate Way,
Manor Park,
Runcorn,
Cheshire
WA7 1NT
United Kingdom

Manufacturer
Fresenius Kabi Austria GmbH
Hafnerstrasse 36
A-8055 Graz
Austria

This leaflet was last revised in December 2014

The following information is intended for healthcare professionals only:

Posology and method of administration

For continuous peripheral intravenous application.
The daily dosage depends on the individual fluid needs of the patient.

Maximum daily dose is 40 ml Aminoven 3.5% Glucose/Electrolytes per kg body weight (equivalent to 1.4 g amino acids per kg body weight and 2.0 g glucose per kg body weight).

Maximum infusion rate is 1.7 ml Aminoven 3.5% Glucose/Electrolytes per kg body weight per hour (equivalent to 0.06 g amino acids per kg body weight and hour and 0.085 g glucose per kg body weight and hour).

If given as the sole source of nutrition Aminoven 3.5% Glucose/Electrolytes can be used for a maximum of one week in patients with a satisfactory to good nutritional condition and with mild to moderate catabolism.

Overdose (symtoms, emergency procedure, antidotes)

As with other amino acid solutions shivering, vomiting, nausea, and increased renal amino acid losses can occur when Aminoven 3.5% Glucose/Electrolytes is given in overdose or the infusion rate is exceeded. When Aminoven 3.5% Glucose/Electrolytes is given in overdose fluid overload, hyperglycaemia and electrolyte disturbances may occur. Infusion should be stopped immediately in this case. It

may be possible to continue with a reduced dosage.

There is no specific antidote for overdose. Infusion should be stopped immediately in such cases. Emergency procedures should be general supportive measures, with particular attention to respiratory and cardiovascular systems. Close biochemical monitoring would be essential and specific abnormalities treated appropriately.

Storage

Do not store above 25°C. Keep container in the outer carton. Do not freeze.

Storage precautions after mixing with other components:

Aminoven 3.5% Glucose/Electrolytes may be aseptically admixed with other nutrients such as fat emulsions, carbohydrates and electrolytes. Chemical and physical stability data for a number of admixtures stored at 4°- 8° C for up to 7 days are available from the manufacturer upon request.

From a microbiological point of view, TPN admixtures compounded in uncontrolled or unvalidated conditions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally be no longer than 24 hours at 2 to 8°C, unless mixing has taken place in controlled and validated aseptic conditions.

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Aminoven 3.5% Glucose/Electrolytes Solution for infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- What is in this leaflet:**
1. What Aminoven 3.5% is and what it is used for
 2. What you need to know before you receive Aminoven 3.5%
 3. How you are given Aminoven 3.5%
 4. Possible side effects
 5. How to store Aminoven 3.5%
 6. Contents of the pack and other information

1. What Aminoven 3.5% is and what it is used for

Aminoven 3.5% provides nourishment 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) together with energy (glucose) and salts.

Aminoven 3.5% is typically mixed with vitamins, lipids and carbohydrates which together provide your complete nutritional needs.



2. What you need to know before you receive Aminoven 3.5%

Do not use Aminoven 3.5%: You should not receive Aminoven 3.5% if you are suffering from, or have suffered from:

- a condition where your body has problems using **proteins or amino acids**
- **metabolic acidosis** (the acid levels of your body fluids and tissues become too high)
- reduced **kidney** function
- seriously reduced **liver** function
- **fluid** retention (hyperhydration)
- **fluid on your lungs** (pulmonary oedema)
- **shock**
- **coma**
- **Insulin-refractory hyperglycaemia** (too much sugar in your blood) where the administration of more than 6 units of insulin per hour is required
- **hypoxia** (low levels of oxygen)
- heart problems
- **dehydration** with low levels of salts
- **low** levels of **sodium** (hyponatraemia)
- **high** levels of **potassium** (hyperkalaemia)
- diabetes
- **severe sepsis** (a condition in which your body is fighting a severe infection)

Warnings and precautions

Care should be taken when administering Aminoven 3.5%

Inform your doctor if you:

- suffer from **low levels of potassium** (hypokalaemia)
- suffer from **low levels of sodium** (hyponatraemia)
- suffer from **folate deficiency**
- suffer from **heart failure** (cardiac insufficiency)

Your doctor will perform regular tests to confirm that your serum electrolytes, fluid balance, kidney function and blood glucose levels are controlled.

The doctor or nurse will check that the solution is particle free before usage.

Children

Aminoven 3.5% is not recommended for newborns, infants and children under 12 years of age or weighing less than 40 kg.

Other medicines and Aminoven 3.5%

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant, if you think you are pregnant or if you are breast-feeding. The doctor will decide if you should receive Aminoven 3.5%.

Driving and using machines

Aminoven 3.5% infusion has no effect on driving or using machines.

3. How to use Aminoven 3.5%

You will receive your medicine by infusion (IV drip). The amount and rate at which the infusion is given depends on your requirements. Your doctor will decide on the correct dose for you to receive. You may be monitored during your treatment.

If you use more Aminoven 3.5% than you should

It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. The effects of an overdose may include nausea, vomiting and shivering.

Hyperglycaemia (too much sugar in your blood) and electrolyte disturbances have also been reported.

If you experience these symptoms or believe that you have received too much Aminoven 3.5% inform your doctor or nurse immediately. The infusion will be stopped immediately if this happens. It may be possible to continue with a reduced dosage. These symptoms will usually disappear on reducing the rate or stopping the infusion. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Aminoven 3.5% can cause side effects, although not everybody gets them. Allergic reaction against any of the ingredients may occur.

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

- 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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting scheme. By reporting side effects you can help provide more information on the safety of this medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aminoven 3.5%

Keep this medicine out of the reach and sight of children.

Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Aminoven 3.5% infusion. Do not store above 25°C. Do not freeze and always keep the container in the outer carton.

The solution must not be used after the expiry date shown on the label.

Any solution remaining after treatment should be disposed of via approved hospital procedures.

6. Contents of the pack and other information

What Aminoven 3.5% solution for infusion contains

Each 1000 ml of Aminoven 3.5% contains the following active ingredients:

Active ingredients	Quantity (g)
Tyrosine	0.14
Isoleucine	1.75
Leucine	2.59
Lysine hydrochloride	2.885 (corresponds to 2.31 Lysine)
Methionine	1.505
Phenylalanine	1.785
Threonine	1.54
Tryptophan	0.70
Valine	2.17
Arginine	4.20
Histidine	1.05
Alanine	4.90