Aminoven 3.5% provides nourishment into your bloodstream 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% 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.
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
  - severely reduced liver function
  - dehydration with low levels of salts
  - low levels of sodium (hyponatraemia)
  - high levels of potassium (hyperkalaemia)
  - severe sepsis
  - diabetes
  - high levels of sugar
  - low levels of sugar (hypoglycaemia)
  - low levels of oxygen
  - heart problems
  - hypoxia
  - high levels of nitrogen (hyperammonaemia)
  - seriously reduced liver function
  - reduced kidney function
  - serious liver problems
  - renal failure
  - hypoxia
  - 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 is a condition in which your body is fighting a severe infection

Warnings and precautions

Care should be taken when administering 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
  - severely reduced liver function
  - dehydration with low levels of salts
  - low levels of sodium (hyponatraemia)
  - high levels of potassium (hyperkalaemia)
  - severe sepsis
  - diabetes
  - severe sepsis is a condition in which your body is fighting a severe infection

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 that 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 breastfeeding

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 than Aminoven 3.5% than 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:

- Fasted deficiency
- Thrombosis (the formation of a clot) in the vein where the injection is given
- 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 the national reporting scheme. 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 contain

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

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>Quantity (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine</td>
<td>2.59</td>
</tr>
<tr>
<td>Arginine</td>
<td>2.47</td>
</tr>
<tr>
<td>Aspartic acid</td>
<td>0.90</td>
</tr>
<tr>
<td>Cystine</td>
<td>1.44</td>
</tr>
<tr>
<td>Glutamic acid</td>
<td>2.59</td>
</tr>
<tr>
<td>Histidine</td>
<td>1.05</td>
</tr>
<tr>
<td>Isoleucine</td>
<td>1.75</td>
</tr>
<tr>
<td>Leucine</td>
<td>2.59</td>
</tr>
<tr>
<td>Lysine</td>
<td>2.855</td>
</tr>
<tr>
<td>Methionine</td>
<td>1.785</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>1.54</td>
</tr>
<tr>
<td>Threonine</td>
<td>0.90</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>2.17</td>
</tr>
<tr>
<td>Valine</td>
<td>4.90</td>
</tr>
<tr>
<td>HClideine</td>
<td>0.10</td>
</tr>
<tr>
<td>Alanine</td>
<td>4.90</td>
</tr>
</tbody>
</table>

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.