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**Directions for Use**

B. Braun Melsungen AG, 34209 Melsungen, Germany

# Aminoplasmal® Hepa – 10 %

# امائنو پلازمال® ھیپا – ۱۰%

**Composition**

1000 ml of solution contain

| | |
|---|---|
| *Active ingredients:* | |
| Isoleucine | 8.80 g |
| Leucine | 13.60 g |
| Lysine Acetate (equivalent to Lysine, 7.51 g) | 10.60 g |
| Methionine | 1.20 g |
| Phenylalanine | 1.60 g |
| Threonine | 4.60 g |
| Tryptophan | 1.50 g |
| Valine | 10.60 g |
| Arginine | 8.80 g |
| Histidine | 4.70 g |
| Glycine (Aminoacetic Acid) | 6.30 g |
| Alanine | 8.30 g |
| Proline | 7.10 g |
| Aspartic Acid | 2.50 g |
| Asparagine Monohydrate (equivalent to Asparagine, 0.48 g) | 0.55 g |
| Acetylcysteine (equivalent to Cysteine, 0.59 g) | 0.80 g |
| Glutamic Acid | 5.70 g |
| Ornithine Hydrochloride (equivalent to Ornithine, 1.30 g) | 1.66 g |
| Serine | 3.70 g |
| Acetyltyrosine (equivalent to Tyrosine, 0.70 g) | 0.86 g |
| *Excipients:* | |
| Disodium edetate dihydrate | 0.05 g, |
| Hydrochloric acid or sodium hydroxide for pH adjustment, water for injections. | |
| Total amino acids | 100 g/l |
| Total nitrogen | 15.3 g/l |
| α-amino nitrogen | 11.2 g |
| Caloric value | 1675 kJ/l = 400 kcal/l |
| Osmolarity | 875 mOsm/l |
| *Electrolyte concentrations:* | |
| Acetate | 51 mmol/l |
| Chloride | 10 mmol/l |

**Pharmaceutical form**

Solution for infusion

**Pharmaco-therapeutic group**

Solution for supply of amino acids

**Indications**

Supply of amino acids in the setting of parenteral nutrition of patients with severe liver insufficiency and imminent or manifest hepatic encephalopathy.

**Contraindications**

- Disorders of amino acid metabolism of other than hepatic origin,
- Severely impaired circulatory status with vital threat (shock),
- Acute pulmonary oedema,
- Acidosis,
- Hyperhydration,
- Hypokalaemia,
- Hyponatraemia,
- Hypersensitivity to any of the ingredients of Aminoplasmal Hepa – 10 %

No data are available on the use of Aminoplasmal Hepa – 10 % in children under 2 years. Therefore, administration of the solution to such patients cannot be recommended until relevant data become available.

Because of the particulars of its composition, Aminoplasmal Hepa - 10 % may cause marked metabolic disturbances if given for other reasons than stated under "Indications". Unindicated use must strictly be avoided.

**Special warnings and precautions for use**

Because of its composition, Aminoplasmal Hepa - 10 % should be administered to patients with concomitant renal insufficiency only after individual benefit/risk assessment.

The dose should be adjusted according to the serum urea and creatinine concentrations.

Caution is also to be exercised in patients with increased serum osmolarity.

Do not administer via peripheral venous catheter.

Amino acid therapy is not a substitute for established therapeutic measures, such as purging, administration of lactulose and/or gut sterilising antibiotics, in the treatment of hepatic encephalopathy.

Infusion of Aminoplasmal Hepa - 10 % should be accompanied by appropriate carbohydrate supply.

Electrolytes are to be supplemented according to actual requirements.

During parenteral therapy fluid and electrolyte balance, serum osmolarity, acid-base balance, blood glucose and liver function should be monitored. Type and frequency of the examinations depend on the severity of the patient's disease and clinical condition.

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2 Seiten

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In particular, regular and more frequent clinical examinations and laboratory tests are necessary in patients with disorders of amino acid metabolism.

**Special precautions for use in paediatrics:**
The dosage must be adjusted according the patient's age, nutritional status and the prevailing disease. In the case of supplementary or partial parenteral nutrition further protein supplying nutrients may have to be given.
An infusion from one bottle should not be carried out over longer than 24 hours.
For complete parenteral nutrition, administration of carbohydrates, essential fatty acids, vitamins and trace elements is necessary.

**Pregnancy and lactation**
No data are available on the use of Aminoplasmal Hepa – 10 % in these situations. It is likely that the conditions in which the product is indicated exclude pregnancy or breast-feeding.

**Interactions**
Because of the risk of microbial contamination and physico-chemical incompatibility, it is not recommended that any additives should be incorporated into Aminoplasmal Hepa - 10 % solution, but should preferably be given in standard carbohydrate or electrolyte solutions.
However, if admixture with Aminoplasmal Hepa - 10 % is essential then the compatibility of the additive must be checked before administration.

**Dosage**
Depending on individual requirements:

| | |
|---|---|
| Normal dose: | 7 – 10 ml /kg BW/day, corresponding to 0.7 – 1.0 g of amino acids/kg BW/day. |
| Maximum dose: | 15 ml /kg BW/day, corresponding to 1.5 g of amino acids/kg BW/day. |

*Flow rate:*
**Treatment of hepatic coma**
In hepatic encephalopathy, it is recommended to start the infusion of Aminoplasmal Hepa - 10 % at an increased rate, until onset of the effect, for example for a patient weighing 70 kg:
1st to 2nd hour: 150 ml/h (2 ml/kg BW/h), corresponding to approx. 50 drops/min,
3rd to 4th hour: 75 ml/h (1 ml/kg BW/h), corresponding to approx. 25 drops/min,
from 5th hour: 45 ml/h (0.6 ml/kg BW/h), corresponding to approx. 15 drops/min.

**Maintenance requirements/parenteral nutrition**
45 – 75 ml/h, corresponding to 15 – 25 drops/min (0.6 – 1.0 ml/kg BW/h)

*Duration of use:*
Aminoplasmal Hepa - 10 % may be administered as long as there is a risk of manifestation of hepatic encephalopathy

*Method of administration*
Intravenous infusion into the *vena cava*

**Overdose**
*Symptoms*
Overdosage or a too rapid infusion rate may manifest in the form of nausea, shivering, vomiting, and renal amino acid losses.

*Emergency treatment, antidotes*
In such cases the infusion should be interrupted and later continued at a lower infusion rate.

**Undesirable effects**
Provided contraindications, dosage recommendations and precautions are observed, side effects are not to be expected.

**Note:**
Patients should inform their doctor or pharmacist if they notice any adverse effect in connection with the administration of this medicine.

**Expiry date**
The product must not be used beyond the expiry date stated on the labelling.

**Storage**
Keep containers in the outer carton in order to protect the contents from light.
**Do not store above 25°C.**

**Instructions for use**
The product is supplied in single-use containers. Administer immediately after connecting the container to the giving set. Unused contents must be discarded and should not be stored for later use.
The solution should not be administered if it is not clear or if the container or its closure show visible signs of damage.

**Date of last revision:**
05.2004

بوتل لیک یا محلول شفاف نہ ہونے کی صورت میں استعمال نہ کریں۔
25°C سے زیادہ درجہ حرارت پر نہ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔

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