Package leaflet: Information for the user

Aminoplasmal 10% Solution for Infusion

Amino acids

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 Aminoplasmal 10% is and what it is used for

Aminoplasmal 10% is a solution which is given to you through a small tube with a cannula placed in a vein (intravenous infusion).
The solution contains amino acids that are essential for the body to grow or to recover.
You will receive this medicine if you are unable to eat food normally and you cannot be fed through a tube placed into your stomach either. This solution can be given to adults, adolescents and children over 2 years of age.

2. What you need to know before you use Aminoplasmal 10%

Do not use Aminoplasmal 10%
- if you are allergic to any of the active substances or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from an inborn error of your metabolism of proteins and amino acids
- if you have a severe (i.e. life-threatening) circulation disorder (shock)
- if you have insufficient oxygen supply (hypoxia)
- if acidic substances accumulate in your blood (metabolic acidosis)
- if you suffer from a poorly controlled heart failure with marked impairment of your blood circulation (decompensated cardiac insufficiency)
- if you have accumulation of fluid in your lungs (acute pulmonary oedema)
- if body water is excess and your limbs swells (hyperhydration)

Your doctor will also take into account that amino acid containing solutions in general must not be used:
- if you have a severe liver disease (severe hepatic insufficiency)
- if you have severe kidney failure (severe renal insufficiency) not adequately treated by artificial kidney or similar therapies

Newborn babies, infants and toddlers less than two years of age

This solution must not be given to newborn babies, infants and toddlers less than two years of age because the composition of the solution does not properly meet the special nutrition requirements of this age group.

Warnings and precautions

Talk to your doctor before Aminoplasmal 10% is administered.
- if you suffer from an impairment of your metabolism of proteins and amino acids caused by any condition other than mentioned above (see section "Do not use …")
- if you have an impairment of your liver or kidney function
- if you have an impairment of your heart function
- if you have abnormally high concentrated blood serum (high serum osmolarity)

Additional precautions taken by your doctor
If your body's water or salt balance is disturbed, this condition should be corrected before you receive this medicine. Examples for this condition are a lack of water and salts at the same time (hypotonic dehydration) or a lack of sodium (hyponatraemia) or potassium (hypokalaemia).

Before and while you are receiving this medicine, your blood salt levels, blood sugar levels, the water balance, the acid-base balance, your blood proteins and kidney and liver function will be monitored. For this purpose blood samples will be taken and your urine will be collected and both will be analysed.

Usually you will receive Aminoplasmal 10% as part of intravenous feeding which also includes non-protein energy supplements (carbohydrate solutions, fat emulsions), essential fatty acids, electrolytes, vitamins, fluids and trace elements.

Other medicines and Aminoplasmal 10%

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
If you are pregnant, you will receive this medicine only if the doctor considers it necessary for your recovery. There are no data available about the use of this medicine in pregnant women.

Breast-feeding
At therapeutic doses of Aminoplasmal 10% no effects on the breastfed newborn/infant are anticipated. Nevertheless, breast-feeding is not recommended if women need intravenous feeding at the same time.

Driving and using machines

This medicine is normally given to immobile patients in a controlled setting (emergency treatment, acute treatment in a hospital or a day therapy unit). This will exclude driving and using machines.

3. How to use Aminoplasmal 10%

Aminoplasmal 10% is given by health care professionals.
The doctor will decides how much of this medicine is needed and for how long this medicine will be given to the patients.

The solution will be given through a small plastic tube inserted into a vein.

Patients with kidney or liver disease
The doses will be adjusted according to your individual requirements if you have liver or kidney disease.

Duration of use
This medicine may be used as long as you need intravenous feeding.

If you received more Aminoplasmal 10% than you should
It is unlikely that this occurs because your doctor will determine your daily doses. However, if you receive an overdose or the solution is flowing too fast, you may feel sick, may have to vomit and may experience headache. Also, your blood may contain too much ammonia (hyperammonaemia) and you may lose amino acids in the urine. You may also suffer from too much fluid in your body (hyperhydration), your body's salt balance may be disturbed (electrolyte imbalance) and you may have water on your lungs (pulmonary oedema). If this happens, the infusion will be stopped and started again at a lower infusion rate some time later.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Such side effects are not specifically related to Aminoplasmal 10% but may occur with any kind of intravenous feeding, especially at the beginning.

The following side effects may be serious. If any of the following side effects occur, tell your doctor immediately, he will stop giving you this medicine:

Not known (frequency cannot be estimated from the available data)
- Allergic reactions

Other side effects

Uncommon (may affect up to 1 in 100 people)
- Vomiting, feeling sick

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aminoplasmal 10%

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

Do not use this medicine after the expiry date which is stated on the bottle and carton labels. The expiry date refers to the last day of that month.

Keep the bottle in the outer carton in order to protect from light.
Do not store above 25°C.

Cool storage of the solution, below 15 °C, may lead to formation of crystals, that can, however, be easily dissolved by gentle warming at 25 °C until dissolution is complete. Shake container gently to ensure homogeneity.
Do not freeze.
After infusion, any remaining solution should never be stored for later use.

6. Contents of the pack and other information

What Aminoplasmal 10% contains

The active substances are amino acids.

This medicine contains:

	per 1 ml	per 250 ml	per 500 ml	per 1000 ml
Isoleucine	5.00 mg	1.25 g	2.50 g	5.00 g
Leucine	8.90 mg	2.23 g	4.45 g	8.90 g
Lysine monohydrate	3.12 mg	0.78 g	1.56 g	3.12 g
(equivalent to lysine)	(2.78 mg)	(0.70 g)	(1.39 g)	(2.78 g)
Lysine acetate	5.74 mg	1.44 g	2.87 g	5.74 g
(equivalent to lysine)	(4.07 mg)	(1.02 g)	(2.04 g)	(4.07 g)
Methionine	4.40 mg	1.10 g	2.20 g	4.40 g
Phenylalanine	4.70 mg	1.18 g	2.35 g	4.70 g
Threonine	4.20 mg	1.05 g	2.10 g	4.20 g
Tryptophan	1.60 mg	0.40 g	0.80 g	1.60 g
Valine	6.20 mg	1.55 g	3.10 g	6.20 g
Arginine	11.50 mg	2.88 g	5.75 g	11.50 g
Histidine	3.00 mg	0.75 g	1.50 g	3.00 g
Alanine	10.50 mg	2.63 g	5.25 g	10.50 g
Glycine	12.00 mg	3.00 g	6.00 g	12.00 g
Aspartic acid	5.60 mg	1.40 g	2.80 g	5.60 g
Glutamic acid	7.20 mg	1.80 g	3.60 g	7.20 g
Proline	5.50 mg	1.38 g	2.75 g	5.50 g
Serine	2.30 mg	0.58 g	1.15 g	2.30 g
Tyrosine	0.40 mg	0.10 g	0.20 g	0.40 g

The other ingredients are acetylcysteine, citric acid monohydrate (for pH-adjustment) and water for injections.

Electrolyte concentrations

Acetate	28	mmol/l
Citrate	1.0 - 2.0	mmol/l
Total amino acids	100	g/l
Total nitrogen	15.8	g/l
Energy [kJ/l (kcal/l)]	1675	(400)
Theoretical osmolarity [mOsm/l]	864	
Acidity (titration to pH 7.4) [mmol NaOH/l]	approx. 20	
pH	5.7 – 6.3	

What Aminoplasmal 10% looks like and contents of the pack

The solution should only be used if the closure of the container is not damaged and if the solution is clear, colourless up to faintly straw-coloured solution, free from particles.

The product comes in colourless glass bottles of 250 ml, 500 ml and 1000 ml, which are each closed by rubber stoppers.
The 250 ml and 500 ml bottles are available in packs of 10. The 1000 ml bottles are available in packs of 6.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Aminoplasmal B. Braun 10 % Infusionslösung
Czech Republic	Aminoplasmal B. Braun 10 %
Germany	Aminoplasmal B. Braun 10 %
Denmark	Aminoplasmal
Spain	Aminoplasmal B. Braun 10 % solución para perfusión
Finland	Aminoplasmal 16 N/l
Italy	Amixal
Lithuania	Aminoplasmal B. Braun 10 % infuzinis tirpalas
Latvia	Aminoplasmal B. Braun 10 % šķīdums infūzijām
Netherlands	Aminoplasmal B. Braun 10 % E-vrij, oplossing voor infusie
Poland	Aminoplasmal B. Braun 10 %
Portugal	Aminoplasmal B. Braun 10 %
Slovakia	Aminoplasmal B. Braun 10 %
Slovenia	Amixal 100 mg/ml raztopina za infundiranje

United Kingdom B. Braun Aminoplasmal 10 % solution for infusion

This leaflet was last revised in June 2020

The following information is intended for healthcare professionals only:

Method of administration

Intravenous use.
For central venous infusion only.

Dosage
The dosage has to be adjusted according to the individual need of amino acids and fluid depending on the clinical condition of the patient (nutritional status and/or degree of nitrogen catabolism due to underlying disease).
Adults and adolescents from 14 to 17 years
Daily dose:

1.0 – 2.0 g amino acids/kg body weight	≙ 10 – 20 ml/kg body weight
	≙ 700 – 1400 ml for a 70 kg patient

Maximum infusion rate:

0.1 g amino acids/kg body weight/h	≙ 1.0 ml/kg body weight/h
	≙ 1.17 ml/min for a 70 kg patient

Paediatric population
Newborn infants, infants and toddlers less than two years of age
Aminoplasmal 10% is contraindicated in newborn infants, infants and toddlers less than 2 years of age (see section 4.3).

Children and adolescents 2 to 13 years
The dosages for the age groups stated below are average values for guidance. The exact dosage should be adjusted individually according to age, developmental stage and prevailing disease.
Daily dose for children 2 to 4 years old:

1.5 g amino acids/kg body weight	≙ 15 ml/kg body weight

Daily dose for children 5 to 13 years old:

1.0 g amino acids/kg body weight	≙ 10 ml/kg body weight

Critically ill children: For critically ill patients the advisable amino acid intake may be higher (up to 3.0 g amino acids/kg body weight per day).

Maximum infusion rate:

0.1 g amino acids/kg body weight/h	≙ 1.0 ml/kg body weight/h

In the case of amino acid requirements of 1.0 g per kg body weight per day or more, particular attention should be paid to the limitations of fluid input. To avoid fluid overload, amino acid solutions with higher amino acid content may have to be used in such situations.

Renal impairment

In patients with renal insufficiency, the dose must be carefully adjusted according to individual needs, severity of organ insufficiency and the kind of instituted renal replacement therapy (haemodialysis, haemofiltration etc.).

Hepatic impairment
In patients with hepatic insufficiency, the dose must be carefully adjusted according to individual needs and severity of organ insufficiency.

Instructions for handling
Use a sterile giving set for infusion of Aminoplasmal 10%.
If in the setting of complete parenteral nutrition it is necessary to add other nutrients such as carbohydrates, lipids, vitamins, electrolytes and trace elements to this medicinal product, admixing must be performed under strict aseptic conditions. Mix well after admixture of any additive. Aminoplasmal 10% can only be mixed with other nutrients for which compatibility has been documented. Compatibility data for different additives and the corresponding shelf life of such admixtures can be provided on demand by the manufacturer.

Special precaution for storage
The product must not be used if the solution is not clear and colourless up to faintly straw-coloured or the bottle or its closure are damaged. Cool storage of the solution, below 15 °C, may lead to formation of crystals, that can, however, be easily dissolved by gentle warming at 25 °C until dissolution is complete. Shake container gently to ensure homogeneity. Containers are for single use only. Discard container and any unused contents after use.

Shelf life after admixture of additives
Do not refrigerate
From a microbiological point of view, unless the method of opening and mixing precludes the risk of microbial contamination, the product should be used. If not used immediately, in-use storage times and conditions are the responsibility of the user.

For complete information on this medicinal product please refer to the Summary of Product Characteristics.