Package leaflet: Information for the user

Aminoplasmal 15% 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 15% is and what it is used for
2. What you need to know before you use Aminoplasmal 15%
3. How to use Aminoplasmal 15%
4. Possible side effects
5. How to store Aminoplasmal 15%
6. Contents of the pack and other information

1. What Aminoplasmal 15% is and what it is used for

Aminoplasmal 15% 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 15%

Do not use Aminoplasmal 15%
- if you are allergic to any of the active substances or to 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 have severe liver disease (severe hepatic insufficiency)
- if you have severe kidney failure (severe renal insufficiency) not adequately treated by artificial kidney or similar therapies
- if you suffer from a poorly controlled heart failure with marked impairment of your blood circulation (decompensated cardiac insufficiency)
- if you have water on the lungs (lung oedema)

- if body water is excess and your limbs swells (hyperhydration)
- if your body fluid level, the salt concentrations and the acidity of your blood are not in a normal level (Disturbances of the electrolyte and fluid balance)

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, pharmacist or nurse before using Aminoplasmal 15%.

If you have a not inborn disorder of protein metabolism, your doctor will decide very carefully whether or not this medicine can or even must be given to you.

If your heart function is impaired, your daily fluid intake will be controlled very carefully in order to avoid any overload of your circulation.

If the overall concentration of dissolved substances in your blood is too high, your doctor will exercise particular caution in order to avoid worsening of this condition.

If your liver or your kidneys do not work well, your daily dose will be adjusted very carefully according to the impairment of your liver or kidney function and your type of treatment.

If you are lacking water and salts at the same time, you will first receive sufficient amounts of these in order to correct that disorder.

If you are lacking potassium or sodium, you will receive sufficient amounts of these.

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.

To make your intravenous feeding complete, you will also receive carbohydrate solutions and possibly also fat emulsions. Further you will be given essential fatty acids, vitamins, fluids, trace elements and electrolytes as necessary.

Children and adolescents

This solution is not suitable for children under 2 years because of its composition, so they should not receive it.

Other medicines and Aminoplasmal 15%

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
There are no data from the use of Aminoplasmal 15% in pregnant women. If you are pregnant, you will receive this medicine only if the doctor considers it absolutely necessary for your recovery. Aminoplasmal 15 % should only be given to pregnant women after careful consideration.

Breast-feeding
At therapeutic doses of Aminoplasmal 15% no effects on the breastfed newborns/infants are anticipated. Nevertheless, breast-feeding is not recommended if women need intravenous feeding in that time.

Driving and using machines

This medicine has no influence on your ability to drive and use machines.

Aminoplasmal 15% contains sodium.

This medicine contains 121.9 mg sodium (main component of cooking/table salt) in 1000 ml.
This is equivalent to 6,095% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Aminoplasmal 15%

Aminoplasmal 15% is given by health care professionals.
The doctor will decide 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.

Dosage
The amount of solution you are going to receive depends on your requirement of amino acids and fluid and also on your actual condition or disease.

Adults
The usual dose is 6.7 ml to 13.3 ml max. per kg body weight per day.
This corresponds to 1.0 – 2.0 g of amino acids per kg body weight per day.

This solution will be administered to you at a maximum rate of 0.67 ml per kg body weight per hour.

Use in children
Aminoplasmal 15% must not be given to children under 2 years of age (see section 2 'What you need to know before you use...').

The dosage for children is adjusted individually according to age, status of development and clinical condition of the child.

The following may be taken as a guidance for the daily doses:
- For children 2 to 4 years old: 10 ml per kg body weight per day, corresponding to 1.5 g of amino acids per kg body weight per day
- For children 5 to 13 years old: 6.7 ml per kg body weight per day, corresponding to 1.0 g of amino acids per kg body weight per day

- Critically ill children: If your child is critically ill, the amount of amino acids required may be higher (up to 3.0 g amino acids/kg body weight per day).

The rate of infusion should not be higher than 0.67 ml per kg body weight per hour.

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.

Method of administration
This medicine will be administered to you by infusion (drip) in a large central vein.

If you use more Aminoplasmal 15% than you should

Overdose or too rapid infusion may not be tolerated well and you may feel sick, may have to vomit and may experience shivering or headache. Also, your blood may contain too much acidic substances and you may lose amino acids in the urine.

If this occurs, your infusion will be stopped and started again at a lower rate some time later.

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

4. Possible side effects

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

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 include:

Uncommon (affects 1 to 10 users in 1,000):
- Feeling sick, vomiting

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 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 15%

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 label and the carton after "EXP:". The expiry date refers to the last day of that month.

Keep the bottles in the outer carton in order to protect from light.

Do not freeze.

Only to be used if the solution is clear and colourless or faintly straw-coloured and the bottle and its closure are undamaged.

The bottles are for single use only. Any solution remaining after an infusion and the container must be disposed of after use.

6. Contents of the pack and other information

What Aminoplasmal 15% contains

The active substances are amino acids.

The solution contains:

	per 1 ml	per 500 ml	per 1000 ml
Isoleucine	5.850 mg	2.925 g	5.850 g
Leucine	11.400 mg	5.700 g	11.400 g
Lysine monohydrate	8.930 mg	4.465 g	8.930 g
(equivalent to lysine)	(7.950 mg)	(3.975 g)	(7.950 g)
Methionine	5.700 mg	2.850 g	5.700 g
Phenylalanine	5.700 mg	2.850 g	5.700 g
Threonine	5.400 mg	2.700 g	5.400 g
Tryptophan	2.100 mg	1.050 g	2.100 g
Valine	7.200 mg	3.600 g	7.200 g
Arginine	16.050 mg	8.025 g	16.050 g
Histidine	5.250 mg	2.625 g	5.250 g
Alanine	22.350 mg	11.175 g	22.350 g
Glycine	19.200 mg	9.600 g	19.200 g
Aspartic acid	7.950 mg	3.975 g	7.950 g
Glutamic acid	16.200 mg	8.100 g	16.200 g
Proline	7.350 mg	3.675 g	7.350 g
Serine	3.000 mg	1.500 g	3.000 g
Tyrosine	0.500 mg	0.250 g	0.500 g
Acetylcysteine	0.500 mg	0.250 g	0.500 g
(equivalent to cysteine)	(0.370 mg)	(0.185 g)	(0.370 g)

The other ingredients are sodium hydroxide, citric acid monohydrate and water for injections.

1000ml of solution contains:

Amino acid content	150	g/l
Nitrogen content	24	g/l
Sodium	5.3	mmol/l
Energy [kJ/l (kcal/l)]	2505	(600)
Theoretical osmolarity [mOsm/l]	1290	
Acidity (titration to pH 7.4) [mmol	approx.	
NaOH/l	31	
pH	5.7 - 6.3	

What Aminoplasmal 15% looks like and contents of the pack

Aminoplasmal 15% is a solution for infusion. The solution is clear, colourless or faintly straw-coloured.

Aminoplasmal 15% is supplied in glass bottles, sealed with rubber stopper:
- Contents: 500 ml, 1000 ml
- Pack sizes: 1 × 500 ml, 10 × 500 ml, 1 × 1000 ml, 6 × 1000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Germany

Postal address:
34209 Melsungen
Germany

Phone: +49-5661-71-0
Fax: +49-5661-71-4567

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

France	AMINOPLASMAL 25, solution pour perfusion
Germany	AMINOPLASMAL – 15 % elektrolyt- und kohlenhydratfrei
Poland	AMINOPLASMAL 15 %
Spain	AMINOPLASMAL B.BRAUN 15% solución para perfusión
United Kingdom	Aminoplasmal 15% solution for infusion

This leaflet was last revised in November 2017

The following information is intended for healthcare professionals only:

Aminoplasmal 15% should only be mixed with other iv solutions, if compatibility has been proven in advance. Compatibility data for different additives (e.g. glucose, lipids, electrolytes, trace elements, vitamins) and the corresponding shelf-life of such admixtures can be provided on demand by the manufacturer.

From a microbiological point of view, mixtures should be administered immediately after preparation. If not administered immediately, storage times and conditions of mixtures prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C – 8°C, unless mixing has taken place under controlled and validated aseptic conditions.

It is essential that any admixture be prepared using strict aseptic techniques as this nutrient mixture supports microbial growth.

Cool storage of the undiluted 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.