Aminoven 15%
Solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION
1000 ml contain:

Active constituents:

Isoleucine	5.20	g
Leucine	8.90	g
Lysine acetate	15.66	g
= Lysine	11.10	g
Methionine	3.80	g
Phenylalanine	5.50	g
Threonine	8.60	g
Tryptophan	1.60	g
Valine	5.50	g
Arginine	20.00	g
Histidine	7.30	g
Alanine	25.00	g
Glycine	18.50	g
Proline	17.00	g
Serine	9.60	g
Tyrosine	0.40	g
Taurine	2.00	g

Other constituents:
Glacial acetic acid
Malic Acid, Water for injections

Total amino acids: Total nitrogen:	150.0 g/l 25.7 g/l
Total energy:	2520 kJ/l (= 600 kcal/l)
pH:	5.5 - 6.3
Titration acidity:	44 mmol NaOH/l
Theoretical osmolarity:	1505 mosm/l

Solution for intravenous infusion

Manufacturer
Fresenius Kabi Austria GmbH, Graz, Austria

Therapeutic indications
For supply of amino acids as part of a parenteral nutrition regimen. **Aminoven 15%** is mainly indicated if during parenteral nutrition therapy the fluid volume has to be restricted.

Amino acid solutions should be administered generally in combination with adequate amount of energy supplements.

Contraindications
As for all amino acid solutions the administration of **Aminoven 15%** is contraindicated in the following conditions:
Disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency without haemodialysis or haemofiltration treatment, advanced liver insufficiency, fl uid overload, shock, hypoxia, decompensated heart failure.

The administration of **Aminoven 15%** is contraindicated in **children**.

For parenteral nutrition of infants and children paediatric amino acid preparations should be used, which are formulated to meet the different metabolic needs of children.

No clinical studies have been conducted with **Aminoven 15%** solution in newborns, infants or children.

Special warnings and precautions for use
Serum electrolytes, fluid balance and renal function should be monitored.

In cases of hypokalemia and/or hyponatremia adequate amounts of potassium and/or sodium should be supplied simultaneously.

Amino acid solutions may precipitate acute folate deficiency, folic acid should therefore be given daily.

Care should be exercised in the administration of large volume infusion fluids to patients with cardiac insufficiency.

No specific studies have been performed to assess the safety of **Aminoven 15%** in pregnancy or lactation. However, clinical experiences with similar parenteral amino acid solution have shown no evidence of risk during pregnancy or breastfeeding. The risk/benefit relationship should be considered before administering **Aminoven 15%** during pregnancy or breast-feeding.

Infusion via peripheral veins in general can cause irritation of the vein wall and thrombophlebitis. Therefore, daily inspections of the insertion site are recommended.
If adjunction of lipid emulsions is indicated it should be administered when possible as a mixture with **Aminoven 15%** in order to minimise the risk of vein irritation.

The choice of a peripheral or central vein depends on the final osmolarity of the mixture. The general accepted limit for peripheral infusion is about 800 mosm/l, but it varies considerably with the age and the general condition of the patient and the characteristics of the peripheral veins.

Strict asepsis should be maintained, particularly when inserting a central vein catheter.

Aminoven 15% is applicable as part of total parenteral nutrition regimen in combination with adequate amounts of energy supplements (carbohydrate solutions, fat emulsions), electrolytes, vitamins and trace elements.

Interactions with other medications
No interactions are known to date.

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Due to the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other drugs. When admixed with other nutrients like carbohydrates, lipid emulsions, electrolytes, vitamins and trace elements attention should be given to compatibility. Aseptic technique and thorough mixing should be used.

Compatibility data are available from the manufacturer for a number of mixtures.

Posology and method of administration
For administration via a central vein as a continuous infusion.

Dosage depends on the severity of the catabolic state and on the amino acid requirement. A maximum daily dosage of 2 g amino acids/ kg body weight should not be exceeded in parenteral nutrition.

Daily dose:
6.7 - 13.3 ml of **Aminoven 15%** per kg body weight (equivalent to 1.0 - 2.0 g amino acids per kg body weight) corresponding to 470 - 930 ml **Aminoven 15 %** at 70 kg body weight.

Maximum infusion rate:
0,67 ml of **Aminoven 15%** per kg body weight per hour (equivalent to 0.1 g amino acids per kg body weight and hour).

The recommended infusion period is to provide a continuous infusion for at least 14 hours up to 24 hours, depending on the clinical situation. Bolus administration is not recommended.

Maximum daily dose:
13.3 ml of **Aminoven 15%** per kg body weight (equivalent to 2.0 g amino acids per kg body weight) corresponding to 140 g amino acids at 70 kg body weight.

The solution is administered as long as a parenteral nutrition is required.

Overdose (symtoms, emergency procedure, antidotes)
As with other amino acid solutions shivering, vomiting, nausea, and increased renal amino acid losses can occur when **Aminoven 15%** is given in overdose or the infusion rate is exceeded. Infusion should be stopped immediately in this case. It may be possible to continue with a reduced dosage.
A too rapid infusion can cause fluid overload and electrolyte disturbances.

There is no specific antidote for overdose. 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.

Undesirable effects
None known when correctly administered. Those that occur during overdose (see above) are usually reversible and regress when therapy is discontinued. Infusion via peripheral veins in general can cause irritation of the vein wall and thrombophlebitis.

No other adverse events have been reported than these that can be seen in connection with parenteral nutrition in general.

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

Aminoven 15% should be used with sterile transfer equipment immediately after opening. Any unused solution should be discarded.
For single use only.
Do not use **Aminoven 15%** after expiry date. Use only clear, particle-free solutions and undamaged containers.

Aminoven 15% 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°C for up to 9 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.

Pack sizes
Glass bottle 250 ml, 500 ml and 1000 ml.

Type II colourless glass bottle, rubber closure/ aluminium cap.

Bottle sizes: 10 x 250 ml glass bottle, 10 x 500 ml glass bottle, 6 x 1000 ml glass bottle.

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