Aminoven 5%
Solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION
1000 ml contain:

Active constituents:

Isoleucine	2.50	g
Leucine	3.70	g
Lysine acetate	4.655	g
= Lysine	3.30	g
Methionine	2.15	g
Phenylalanine	2.55	g
Threonine	2.20	g
Tryptophan	1.00	g
Valine	3.10	g
Arginine	6.00	g
Histidine	1.50	g
Alanine	7.00	g
Glycine	5.50	g
Proline	5.60	g
Serine	3.25	g
Tyrosine	0.20	g
Taurine	0.50	g

Other constituents:
Glacial acetic acid
Water for injections

Total amino acids:	50.0 g/l
Total nitrogen:	8.1 g/l
Total energy:	840 kJ/l (= 200kcal/l)
pH:	5.5 - 6.3
Titration acidity:	12 mmol NaOH/l
Theoretical osmolarity:	495 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.
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 5%** is contra-indicated in the following conditions:
Disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency without haemodialysis or haemofiltration treatment, advanced liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure.

The administration of **Aminoven 5%** is contraindicated in neonates.

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 5%** 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 5%** 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 5%** 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 5%** 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 5% 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.

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 peripheral or central vein as a continuous infusion.

Daily dose:
16 - 20 ml of **Aminoven 5%** per kg body weight (equivalent to 0.8 - 1.0 g amino acids per kg body weight) corresponding to 1120 - 1400 ml **Aminoven 5 %** at 70 kg body weight.

Maximum infusion rate:
2.0 ml of **Aminoven 5%** per kg body weight per hour (equivalent to 0.1 g amino acids per kg body weight and hour).

Maximum daily dose:
20 ml of **Aminoven 5%** per kg body weight (equivalent to 1.0 g amino acids per kg body weight) corresponding to 70 g amino acids at 70 kg body weight.
The solution is administered as long as a parenteral nutrition is required.

For an increased amino acids dosage suitable preparations are available.

Overdose (symtoms, emergency procedure, antidotes)
As with other amino acid solutions shivering, vomiting, nausea, and increased renal amino acid losses can occur when **Aminoven 5%** 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 below) 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 5% should be used with sterile transfer equipment immediately after opening. Any unused solution should be discarded.
Do not use **Aminoven 5%** after expiry date.
Use only clear, particle-free solutions and undamaged containers.

Aminoven 5% 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.

Packsizes
Bottles of 500 ml and 1000 ml.

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FRESENIUS KABI