1. TRADE NAME OF THE MEDICINAL PRODUCT

Aminoven 5%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml solution for infusion contain:

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

Total amino acids:	50.0 g/l
Total nitrogen:	8.1 g/l
Total energy:	840 kJ/l (= 200kcal/l)

pH	:	5.5 - 6.5
Titratable acidity	:	12 mmol NaOH/l
Theoretical osmolarity	:	495 mosm/l

3. PHARMACEUTICAL FORM

Solution for infusion

4. CLINICAL PARTICULARS

4.1 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.

4.2 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.

4.3 Contra-indications

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 contra-indicated in neonates.
For parenteral nutrition of infants and small children 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.

4.4 Special warnings and special 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.

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 where 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.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known to date.

Please also refer to section 6.2 „Incompatibilities“

4.6 Use during pregnancy and lactation

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 solutions have shown no evidence of risk during pregnancy or breastfeeding. The risk/benefit relationship should be considered before administering Aminoven 5% during pregnancy or breastfeeding.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 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 clinical studies have been conducted.

4.9 Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B05B A01 - amino acids - solution for parenteral nutrition

The amino acids contained in **Aminoven 5%** are all naturally occuring physiological compounds. As with the amino acids derived from the ingestion and assimilation of food proteins, parenterally administered amino acids enter the body pool of free amino acids and all subsequent metabolic pathways.

5.2 Pharmacokinetic properties

The amino acids in **Aminoven 5%** enter the plasma pool of corresponding free amino acids. From the intravascular space, amino acids distribute to the interstitial

fluid and, are individually regulated for each single amino acid, into the intracellular space of different tissues as required.
Plasma and intracellular free amino acid concentrations are endogenously regulated within narrow ranges, depending on the age, nutritional status and pathological condition of the patient.
Balanced amino acid solutions such as **Aminoven 5%** do not significantly alter the physiological amino acid pool when infused at a constant and slow infusion rate.

Characteristic changes in the physiological amino acid pool of the plasma are only foreseeable when the regulative function of essential organs like liver and kidneys are seriously impaired. In such cases special formulated amino acid solutions may be recommended for restoring homeostasis.

Only a small proportion of the infused amino acids is eliminated by the kidneys.
For the majority of amino acids plasma half-lives between 10 and 30 minutes have been reported.

5.3 Preclinical safety data

Preclinical toxicity data are available for single amino acids but are not relevant to mixtures of amino acids in solutions such as **Aminoven 5%**. No preclinical toxicity studies with **Aminoven 5%** have been carried out, but studies with comparable amino acid solutions have shown no toxic effect.

Intravenous infusion of doses of **Aminoven 5%** were well tolerated in rabbits. **Aminoven 5%** administered in error by intra-arterial infusion, paravenous, subcutaneous or intramuscular injection to rabbits caused histopathological changes (eg oedema, haemorrhage, lymphohistiocytic infiltration) comparable to those seen in the control animals, but was otherwise well tolerated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glacial acetic acid
Water for injections

6.2 Incompatibilities

Due to the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other medicinal products. Should it become necessary to add other nutrients, see sections 6.3 c), 6.4, 6.6.

6.3 Shelf life

a) Shelf-life of the medicinal product as packaged for sale

2 years

b) Shelf life after first opening the container

Aminoven 5% should be used with sterile transfer equipment immediately after opening. Any unused solution should be discarded.

c) Shelf-life after mixing with other components

In general, TPN admixtures may be stored for a maximum period of 24 hours at 2 to 8°C, unless a longer storage period has been proven. See Section 6.4.

6.4 Special precautions for storage

Keep container in the outer carton.
Do not freeze.

Storage precautions after mixing with other components:
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.

6.5 Nature and contents of container

Glass bottles, 500 ml and 1000 ml
Type II, colourless glass, rubber closure/aluminium cap and outer carton.

Package sizes: 10 x 500 ml glass bottle
6 x 1000 ml glass bottle
1 x 500 ml glass bottle (sample package).

6.6 Instructions for use/handling

To be used immediately after the bottle is opened.
For single use only.
Do not use **Aminoven 5%** after expiry date.

Use only clear, particle-free solutions and undamaged containers.

Discard unused solutions. Any admixture remaining after infusion must be discarded.

Due to the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other drugs. Should it become

necessary to add other nutrients, like carbohydrates, lipid emulsions, electrolytes, vitamins or trace elements to **Aminoven 5%** for complete parenteral nutrition, care should be given to aseptic techniques, thorough mixing and, in particular, to compatibility.

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

7. MARKETING AUTHORIZATION HOLDER

Fresenius Kabi

1. TRADE NAME OF MEDICINAL PRODUCT

Aminoven 10%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml solution of infusion contain:

Isoleucine	5.00	g
Leucine	7.40	g
Lysine acetate = Lysine 6.60 g	9.31	g
Methionine	4.30	g
Phenylalanine	5.10	g
Threonine	4.40	g
Tryptophan	2.00	g
Valine	6.20	g
Arginine	12.00	g
Histidine	3.00	g
Alanine	14.00	g
Glycine	11.00	g
Proline	11.20	g
Serine	6.50	g
Tyrosine	0.40	g
Taurine	1.00	g

Total amino acids:	100.0 g/l
Total nitrogen:	16.2 g/l
Total energy:	1680 kJ/l (= 400 kcal/l)

pH	:	5.5 - 6.5
Titratable acidity	:	22 mmol NaOH/l
Theoretical osmolarity	:	990 mosm/l

3. PHARMACEUTICAL FORM

Solution for infusion

4. CLINICAL PARTICULARS

4.1 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.

4.2 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:
10 - 20 ml of **Aminoven 10%** per kg body weight (equivalent to 1.0 - 2.0 g amino acids per kg body weight) corresponding to 700 - 1400 ml **Aminoven 10%** at 70 kg body weight.

Maximum infusion rate:
1.0 ml of **Aminoven 10%** 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 10%** per kg body weight (equivalent to 2.0 g amino acids per kg body weight) corresponding to 1400 ml **Aminoven 10%** or 140 g amino acids at 70 kg body weight.

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

4.3 Contra-indications

As for all amino acid solutions the administration of **Aminoven 10%** 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 is contra-indicated in neonates.
For parenteral nutrition of infants and small children 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 10% solution in newborns, infants or children.

4.4 Special warnings and special 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.

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 10% is applicable as part of a total parenteral nutrition regimen in combination with adequate amounts of energy supplements (carbohydrate solutions, fat emulsions), electrolytes, vitamins and trace elements.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known to date.

Please also refer to section 6.2 „Incompatibilities“

4.6 Use during pregnancy and lactation

No specific studies have been performed to assess the safety of **Aminoven 10%** in pregnancy or lactation. However, clinical experiences with similar parenteral amino acid solutions have shown no evidence of risk during pregnancy or breastfeeding. The risk/benefit
relationship should be considered before administering **Aminoven 10%** during pregnancy or breastfeeding.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 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.

4.9 Overdose

As with other amino acid solutions shivering, vomiting, nausea, and increased renal amino acid losses can occur when **Aminoven 10%** 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B05B A01 - amino acids - solution for parenteral nutrition

The amino acids contained in **Aminoven 10%** are all naturally occuring physiological compounds. As with the amino acids derived from the ingestion and assimilation of food proteins, parenterally administered amino acids enter the body pool of free amino acids and all subsequent metabolic pathways.

5.2 Pharmacokinetic properties

The amino acids in **Aminoven 10%** enter the plasma pool of corresponding free amino acids. From the intravascular space, amino acids distribute to the interstitial fluid and, are individually regulated for each single amino acid, into the intracellular space of different tissues as required.

Plasma and intracellular free amino acid concentrations are endogenously regulated within narrow ranges, depending on the age, nutritional status and pathological condition of the patient.
Balanced amino acid solutions such as **Aminoven 10%** do not significantly alter the physiological amino acid pool when infused at a constant and slow infusion rate.

Characteristic changes in the physiological amino acid pool of the plasma are only foreseeable when the regulative function of essential organs like liver and kidneys are seriously impaired. In such cases special formulated amino acid solutions may be recommended for restoring homeostasis.

Only a small proportion of the infused amino acids is eliminated by the kidneys.
For the majority of amino acids plasma half-lives between 10 and 30 minutes have been reported.

5.3 Preclinical safety data

Preclinical toxicity data are available for single amino acids but are not relevant to mixtures of amino acids in solutions such as **Aminoven 10%**. No preclinical toxicity studies with **Aminoven 10%** have been carried out, but studies with comparable amino acid solutions have shown no toxic effect.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glacial acetic acid
Water for injections

6.2 Incompatibilities

Due to the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other drugs.

Should it become necessary to add other nutrients, see sections 6.3 c), 6.4, 6.6.

6.3 Shelf-life

a) Shelf-life of the medicinal product as packaged for sale

2 years.

b) Shelf life after first opening the container

Aminoven 10% should be used with sterile transfer equipment immediately after opening. Any unused solution should be discarded.

c) Shelf-life after mixing with other components

In general, TPN admixtures may be stored for a maximum period of 24 hours at 2 to 8°C, unless a longer storage period has been proven. See Section 6.4.

6.4 Special precautions for storage

Keep container in the outer carton.
Do not freeze.

Storage precautions after mixing with other components:

Aminoven 10% 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.

6.5 Nature and contents of container

Glass bottles, 500 ml and 1000 ml
Type II, colourless glass, rubber closure/aluminium cap and outer carton.

Package sizes: 10 x 500 ml glass bottle
6 x 1000 ml glass bottle
1 x 500 ml glass bottle (sample package).

6.6 Instructions for use/handling

To be used immediately after the bottle is opened.
For single use only.
Do not use **Aminoven 10%** after expiry date.

Use only clear, particle-free solutions and undamaged containers.

Discard unused solutions. Any admixture remaining after infusion must be discarded.

Due to the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other drugs. Should it become necessary to add other nutrients, like carbohydrates, lipid emulsions, electrolytes, vitamins or trace elements to **Aminoven 10%** for complete parenteral nutrition, care should be given to aseptic techniques, thorough mixing and, in particular, to compatibility.

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

7. MARKETING AUTHORIZATION HOLDER

Fresenius Kabi

1. TRADE NAME OF MEDICINAL PRODUCT

Aminoven 15%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml solution for infusion contain:

Isoleucine	5.20	g
Leucine	8.90	g
Lysine acetate = Lysine 11.1 g	15.66	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

Total amino acids:	150.0 g/l
Total nitrogen:	25.7 g/l
Total energy:	2520 kJ/l (= 600 kcal/l)

pH	:	5.5 - 6.5
Titratable acidity	:	44 mmol NaOH/l
Theoretical osmolarity	:	1505 mosm/l

3. PHARMACEUTICAL FORM

Solution for infusion

4. CLINICAL PARTICULARS

4.1 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 amounts of energy supplements.

4.2 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 to 930 ml **Aminoven 15 %** at 70 kg body weight.

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

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.

4.3 Contra-indications

As for all amino acid solutions the administration of **Aminoven 15%** 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 15%** is contra-indicated in neonates.
For parenteral nutrition of infants and small children 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.

4.4 Special warnings and special 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.

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 a total parenteral nutrition regimen in combination with adequate amounts of energy supplements (carbohydrate solutions, fat emulsions), electrolytes, vitamins and trace elements.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known to date.

Please also refer to section 6.2 „Incompatibilities“

4.6 Use during pregnancy and lactation

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 solutions have shown no evidence of risk during pregnancy or breastfeeding. The risk/benefit relationship should be considered before administering **Aminoven 15%** during pregnancy or breastfeeding.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 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.

Clinical experience is very limited.

4.9 Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B05B A01 - amino acids - solution for parenteral nutrition

The amino acids contained in **Aminoven 15%** are all naturally occuring physiological compounds. As with the amino acids derived from the ingestion and assimilation of food proteins, parenterally administered amino acids enter the body pool of free amino acids and all subsequent metabolic pathways.

5.2 Pharmacokinetic properties

The amino acids in **Aminoven 15%** enter the plasma pool of corresponding free amino acids. From the intravascular space, amino acids distribute to the interstitial fluid and, individually regulated for each single amino acid, into the intracellular space of different tissues as required.
Plasma and intracellular free amino acid concentrations are endogenously regulated within narrow ranges, depending on the age, nutritional status and pathological condition of the patient.
Balanced amino acid solutions such as **Aminoven 15%** do not significantly alter the physiological amino acid pool when infused at a constant and slow infusion rate.

Characteristic changes in the physiological amino acid pool of the plasma are only foreseeable when the regulative function of essential organs like liver and kidneys are seriously impaired. In such cases special formulated amino acid solutions may be recommended for restoring homeostasis.

Only a small proportion of the infused amino acids is eliminated by the kidneys. For the majority of amino acids plasma half-lives between 10 and 30 minutes have been reported.

5.3 Preclinical safety data

Preclinical toxicity data are available for single amino acids but are not relevant to mixtures of amino acids in solutions such as **Aminoven 15%**. No preclinical toxicity studies with **Aminoven 15%** have been carried out, but studies with comparable amino acid solutions have shown no toxic effect.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glacial acetic acid
Water for injections
Malic acid

6.2 Incompatibilities

Due to the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other medicinal products. Should it become necessary to add other nutrients, see sections 6.3 c), 6.4, 6.6.

6.3 Shelf-life

a) Shelf-life of the medicinal product as packaged for sale

2 years

b) Shelf life after first opening the container

Aminoven 15% should be used with sterile transfer equipment immediately after opening. Any unused solution should be discarded.

c) Shelf-life after mixing with other components

In general, TPN admixtures may be stored for a maximum period of 24 hours at 2 to 8°C, unless a longer storage period has been proven. See Section 6.4.

6.4 Special precautions for storage

Keep container in the outer carton.
Do not freeze.

Storage precautions after mixing with other components:
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.

Nature and contents of container

Glass bottles, 250 ml, 500 ml and 1000 ml
Type II, colourless glass, rubber closure,/aluminium cap and outer carton.

Package sizes: 10 x 250 ml glass bottle
10 x 500 ml glass bottle
6 x 1000 ml glass bottle
1 x 250 ml glass bottle (sample package)

6.6 Instruction for use/handling

To be used immediately after the bottle is opened.
For single use only.
Do not use **Aminoven 15%** after expiry date.
Use only clear, particle-free solutions and undamaged containers.

Discard unused solutions.
Any admixture remaining after infusion must be discarded.

Due to the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other drugs. Should it become necessary to add other nutrients, like carbohydrates, lipid emulsions, electrolytes, vitamins or trace elements to **Aminoven 15%** for complete parenteral nutrition, care

should be given to aseptic techniques, thorough mixing and, in particular, to compatibility.
Compatibility data are available from the manufacturer for a number of mixtures.

7. MARKETING AUTHORIZATION HOLDER

Fresenius Kabi