Leaflet no **335 315** (ersätter)

Tryckspecifikation

Format:	420 x 210 mm
Färger:	PMS svart
Utskrift:	anpassat till A3

3:e korr 14-04-23
Niklas baudin, 018 64 4046

KABIVEN PERIPHERAL
Amino acids, Glucose, Electrolytes, Soybean oil

COMPOSITION
1000 kcal
1440 ml before mixture contain :
Each 885 ml glucose 11% contain :

Glucose monohydrate	107 g
corresponding to Glucose (anhydrous)	97 g
water for injection ad	885 ml

Each 300 ml Vamin 18 Novum contain :

L-Alanine	4.8 g
L-Arginine	3.4 g
L-Aspartic acid	1.0 g
L-Glutamine acid	1.7 g
Glycine	2.4 g
L-Histidine	2.0 g
L-Isoleucine	1.7 g
L-Leucine	2.4 g
L-Lysine hydrochloride	3.4 g
corresp. To L-Lysine	2.7 g
L-Methionine	1.7 g
L-Phenylalanine	2.4 g
L-Proline	2.0 g
L-Serine	1.4 g
L-Threonine	1.7 g
L-Tryptophane	0.57 g
L-Tyrosine	0.069 g
L-Valine	2.2 g
Calcium chloride 2 H_2O	0.29 g
corresp. to Calcium chloride	0.22 g
Sodium glycerophosphat (anhydrous)	1.5 g
Magnesium sulphate 7H_2O	0.99 g
corresp. to Magnesium sulphate	0.48 g
Potassium chloride	1.8 g
Sodium acetate 3H_2O	2.5 g
corresp. to Sodium acetate	1.5 g
Acetic acid glacial	Adjust pH approx. 5.6
Water for injection ad	300 ml

Each 255 ml Intralipid 20% contain :

Purified soybean oil	51 g
Purified egg phospholipids	3.1 g
Glycerol	5.6 g
Sodium hydroxide	Adjust pH approx.8
Water for injection ad	255 ml

1400 kcal
1920 ml before mixture contain :
Each 1180 ml glucose 11% contain :

Glucose monohydrate	143 g
corresponding to Glucose (anhydrous)	130 g
Water for injection ad	1180 ml

Each 400 ml Vamin 18 Novum contain :

L-Alanine	6.4 g
L-Arginine	4.5 g
L-Aspartic acid	1.4 g
L-Glutamine acid	2.2 g
Glycine	3.2 g
L-Histidine	2.7 g
L-Isoleucine	2.2 g
L-Leucine	3.2 g
L-Lysine hydrochloride	4.5 g
corresp. to L-Lysine	3.6 g
L-Methionine	2.2 g
L-Phenylalanine	3.2 g
L-Proline	2.7 g
L-Serine	1.8 g
L-Threonine	2.2 g
L-Tryptophan	0.76 g
L-Tyrosine	0.092 g
L-Valine	2.9 g
Calcium chloride 2 H_2O	0.39 g
corresp. to Calcium chloride	0.30 g
Sodium glycerophosphat (anhydrous)	2.0 g
Magnesium sulphate 7H_2O	1.3 g
corresp. to Magnesium sulphate	0.64 g
Potassium chloride	2.4 g
Sodium acetate 3H_2O	3.3 g
corresp. to Sodium acetate	2.0 g
Acetic acid glacial	Adjust pH approx. 5.6
Water for injection ad	400 ml

Each 340 ml Intralipid 20% contain :

Purified soybean oil	68 g
Purified egg phospholipids	4.24 g
Glycerol	7.48 g
Sodium hydroxide	Adjust pH approx.8
Water for injection ad	340 ml

1440 ml and 1920 ml of the mixture contain :

Active Ingredient	**1440 ml**	**1920 ml**
Glucose monohydrate	107 g	143 g
corresp. to Glucose (anhydrous)	97 g	130 g
Purified soybean oil	51 g	68 g
Sodium hydroxide	Adjust pH approx. 8	Adjust pH approx.8
L-Alanine	4.8 g	6.4 g
L-Arginine	3.4 g	4.5 g
L-Aspartic acid	1.0 g	1.4 g
L-Glutamine acid	1.7 g	2.2 g
Glycine	2.4 g	3.2 g
L-Histidine	2.0 g	2.7 g
L-Isoleucine	1.7 g	2.2 g
L-Leucine	2.4 g	3.2 g
L-Lysine hydrochloride	3.4 g	4.5 g
corresp. to L-Lysine	2.7 g	3.6 g
L-Methionine	1.7 g	2.2 g
L-Phenylalanine	2.4 g	3.2 g
L-Proline	2.0 g	2.7 g
L-Serine	1.4 g	1.8 g
L-Threonine	1.7 g	2.2 g
L-Tryptophane	0.57 g	0.76 g
L-Tyrosine	0.069 g	0.092 g
L-Valine	2.2 g	2.9 g
Calcium chloride 2 H_2O	0.29 g	0.39 g
corresp. to Calcium chloride	0.22 g	0.30 g
Sodium glycerophosphat (anhydrous)	1.5 g	2.0 g
Magnesium sulphate 7H_2O	0.99 g	1.3 g
corresp. to Magnesium sulphate	0.48 g	0.64 g
Potassium chloride	1.8 g	2.4 g
Sodium acetate 3H_2O	2.5 g	3.3 g
corresp. to Sodium acetate	1.5 g	2.0 g
Acetic acid glacial	Adjust pH approx. 5.6	Adjust pH approx. 5.6
Purified egg phospholipids	3.2 g	5.6 g
Glycerol anhydrous	4.24 g	7.48 g
Water for injection ad	1440 ml	1920 ml
Corresponding to :		
• Amino acids	34 g	45 g
• Nitrogen	5.4 g	7.2 g
• Fat	51 g	68 g
• Carbohydrates		
- Glucose (anhydrous)	97 g	130 g
• Energy content :		
- Total	approx. 1000 kcal	1400 kcal
- Non protein	approx. 900 kcal	1200 kcal
• Electrolytes		
- Sodium		32 mmol
43 mmol		
- Potassium	24 mmol	32 mmol
- Magnesium	4 mmol	5.3 mmol
- Calcium	2 mmol	2.7 mmol
- Phosphate	11 mmol	14 mmol
- Sulphate	4 mmol	5.3 mmol
- Chloride	47 mmol	62 mmol
- Acetate	39 mmol	52 mmol
• Osmolality	approx. 830 mosm/kg water	
• Osmolarity	approx. 750 mosmol/l	
• pH	approx. 5.6	

Mode of Action
Fat emulsion
Intralipid, the fat emulsion used in Kabiven Peripheral, provides essential and non-essential long chain fatty acids for energy metabolism and the structural integrity of cell membranes.

Intralipid in the recommended dosage does not cause haemodynamic changes. No clinically significant changes in pulmonary function have been described when Intralipid is used at appropriate infusion rate. The transient increase in liver enzymes observed in some patients on parenteral nutrition are reversible and disappear when parenteral nutrition is discontinued. Similar changes are also seen in parenteral nutrition without fat emulsions.

Amino Acids and Electrolytes
Amino acids are constituents of protein in ordinary food. They are utilized for tissue protein synthesis and any surplus is channeled towards gluconeogenesis. Infusion of amino acids are associated with email increases in metabolic rate and thermogenesis.

Glucose
Glucose has no pharmacodynamic effects apart from contributing to normal homeostasis.

INDICATION

Parenteral nutrition for patients and children above 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.

DOSAGE AND ADMINISTRATION

The dose should be individualized and the choice of bag size should be made with regard to the patient's clinical condition, body weight and nutritional requirements.

Adult patient
The nitrogen requirements for maintenance of body protein mass depend on the patient's condition (e.g. nutritional state and degree of catabolic stress). The requirements are 0.10 – 0.15 g nitrogen/kg b.w./day in the normal nutritional, the requirements are in the range of 0.15 – 0.30 g nitrogen/kg b.w./day (1.0 – 2.0 g amino acid/kg b.w./day). The corresponding commonly accepted requirements are 2.0 – 6.0 g for glucose and 1.0 – 2.0 g for fat.

The total energy requirement depends on the patient's clinical condition and is often between 20 – 30 kcal/kg b.w/day. In obese patients the dose should be based on the estimated ideal weight. Kabiven Peripheral is produced in the three sizes intended for patients with moderately increased, basal or low nutritional requirements. To provide total parenteral nutritional, the addition of trace elements, vitamins and supplemental electrolytes may be required.

The dose range of 0.10 – 0.15 g N/kg b.w./day (0.7 – 1.0 g amino acid/kg body weight/day) and a total energy of 20 – 30 kcal body weight/day correspond to approx. 27 – 40 ml Kabiven Peripheral/kg b.w/day.

Children
The ability to metabolise individual nutrients must determine the dosage.

In general the infusion for small children (2-10 years) should start with a low dose i/e 14 – 28 ml/kg (corresponding to 0.49 – 0.98 g fat/kg/day, 0.34 – 0.67 g amino acids/kg/day and 0.95 – 1.9 g glucose/kg/ day and increased by 1 – 15 ml/kg/day up to maximum dosage of 40 ml/kg/day.

Infusion rate
The maximum infusion rate for glucose is 0.25 g/kg b.w./h
Amino acid dosage should not exceed 0.1 g/kg b.w./h
Fat dosage should not provide more than 0.15 g/kg b.w./h

The infusion rate should not exceed 3.7 ml/kg b.w/h (corresponding to 0.25 g glucose, 0.09 g amino acids, 0.13 g fat per kg body weight). The recommended infusion period for individual bags of Kabiven Peripheral is 12 – 24 hours.

Maximum daily dose
40 ml/kg b.w/day. This is equal to one bag (largest size) to a 64 kg – patient and will provide 0.96 g amino acids/kg b.w/day and 0.16 g N/kg b.w./day), 25 kcal/b.w/day nonprotein energy (2.7 g glucose/kg b.w./day and 1.4 g fat/kg b.w./day).
The maximum daily dose varies with the clinical condition of the patient and may even change from day to day.

Method and duration of administration
Intravenous infusion into a peripheral or central vein. Infusion may be continued for as long as required by the patient's clinical condition.

In order to minimize the risk of thrombophlebitis for peripheral application, daily rotation of infusion site is recommended.

UNDESIRABLE EFFECT

The infusion may cause a rise in body temperature (incidence < 3%) and less frequently, shivering, chills and nausea / vomiting (incidence < 1%). Transient increases in liver enzymes during intravenous nutrition have also been reported.

As with all hypertonic solutions for infusion, thrombophlebitis may occur if peripheral veins are used.

Reports of other undesirable effects in conjunction with the included components are extremely rare. Hypersensitivity reactions (anaphylactic reaction, skin rash, urticaria), respiratory symptoms (e.g tachypnoea) and hyper / hypotension have been described Haemolysis, reticulocytosis, abdominal pain, headache, nausea, vomiting, tiredness and priapism have been reported.

Fat overload syndrome
An impaired capacity to eliminate fat may lead to the fat overload syndrome. This may occur as a result of overdosage, but also at recommended rates of infusion, in association with a sudden change in the patient's clinical condition resulting in severe renal or hepatic impairment.
The fat overload syndrome is characterized by hyperlipidaemia, fever, hepato – splenomegaly, anaemia, leucopenia, thrombocytopenia, coagulapathies and coma. These changes are invariably reversible on discontinuation of the fat infusion.

CONTRA INDICATION

Known hypersensitivity to egg – or soy protein or to any of the excipients.
Severe hyperlipaemia.
Severe liver insufficiency.
Severe blood coagulation disorders.
Inborn errors of amino acid metabolism.
Severe renal insufficiency without access to haemofiltration or dialysis.
Acute shock.
Hyperglycemia, which requires more than 6 units insulin / h.
Pathologically elevated serum levels of any of the included electrolytes.

General contra – indications to infusion therapy: acute pulmonary oedema, hyper hydration and decompensated cardiac insuffiency and hypotonic dehydration.
Haemophagocytotic syndrome.
Unstable conditions (e.g. severe post – traumatic conditions, uncompensated diabetes, acute myocardial, infraction, metabolic acidosis, severe sepsis and hyperosmolar coma.
Infants and children under 2 years of age.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The ability to eliminate fat should be monitored. It is recommended that this is done by measuring serum triglycerides after a fat – free period of 5 – 6 hours.
The serum concentration of triglycerides should not exceed 3 mmol/l during infusion.

The bag size, specially the volume and the quantitative composition should be carefully chosen. These volumes should be adjusted according to the hydration and nutritional status of the children.
One reconstituted bag is for single use.

Disturbances of the electrolyte and fluid balance (e.g abnormally high or low serum levels of the (electrolytes) should be corrected before starting the infusion.

Special clinical monitoring is required at the beginning of any intravenous infusion. Should any abnormal sign occur, the infusion must be stopped. Since an increased risk of infection is associated with the use of any central vein, strict aseptic precautions should be taken to avoid any contamination during catheter insertion and manipulation.

Kabiven Peripheral should be given with caution in conditions of impaired lipid metabolism due to renal insufficiency, uncompensated diabetes mellitus, pancreatitis impaired liver function, hypothyroidsm (with hypertriglyceridaemia) or sepsis. If Kabiven Peripheral is given to patients with these conditions, close monitoring of serum triglycerides concentrations is mandatory.
Serum glucose, electrolytes and osmolarity as well as fluid balance, acid – base status and liver enzyme tests should be regularly monitored.

Blood cell count and coagulation should be monitored when fat is given for a longer period.

In patients with renal insufficiency, the phosphate and potassium intake should be carefully controlled to prevent hyperphosphataemia and hyperkalemia.
The amount of supplemental electrolytes should be determined by regular monitoring taking into consideration the clinical condition of the patient.

This emulsion is free of vitamins and trace elements.
The addition of trace elements and vitamins is always required. For vitamin supplementation, paediatric formulation is recommended to be used.

Parenteral nutrition should be given with caution to patients with metabolic acidosis (e.g lactic acidosis), increased serum osmolarity or those in need of fluid resuscitation.

Kabiven Peripheral should be given with caution to patients with a tendency towards electrolyte retention.

Any sign or symptom of anaphylactic reaction necessitates immediate interruption of the infusion.

The fat content of Kabiven Peripheral may interfere with certain laboratory measurements (e.g bilirubin, lactate dehydrogenase, oxygen saturation Hb) if blood is sampled before fat has been adequately cleared from the bloodstream. Fat is cleared after a fat – free interval of 5 – 6 hours in most patients.
Intravenous infusion of amino acids may be accompanied by increased urinary excretion of trace elements, particularly zinc. Additional supplements of trace elements may be required in patients requiring long – torm intravenous nutrition.
In malnourished patients, initiation of parenteral nutrition can precipitate fluid shifts resulting in pulmonary oedema and congestive heart failure.

In addition, decreases in the serum concentrations of potassium phosphorus, magnesium and water soluble vitamins may occur within 24 to 48 hours. Careful and slow initiation of parenteral nutrition is recommended together with close monitoring and appropriate adjustments of fluids, electrolytes, minerals and vitamins.

Kabiven Peripheral should not be given simultaneously with blood or blood products in the same infusion set. In patients with hyperglycaemia, administration of exogenous insulin might be necessary.

Peripheral Infusion
As with all hypertonic solutions, thrombophlebitis may occur if peripheral veins are used for infusions. Several factors contribute to the incidence of thrombophlebitis. These include the type of cannula used and its diameter and length, the duration of infusion, pH and osmolality of infustate infection and the number of manipulations. It is recommended that venous access sites for TPN should not be used for other intravenous additives or solutions.

Use during pregnancy and lactations

No specific studies have been performed to assess the safety of Kabiven Peripheral in pregnancy and lactation. The prescriber should consider the benefit risk relationship before administering Kabiven Peripheral to pregnant or breast feeding women.

Overdose

Nausea, vomiting and sweating have been observed during infusion of amino acids at rates exceeding the recommended maximum rate.

If symptoms of overdose occur, the infusion should be slowed down of discontinued additionally, overdose might cause fluid overload, electrolyte imbalance, hyperglycemia and hyperosmolality. In some rare serious cases, haemodialysis, haemofiltartion or haemo – diafiltration may be necessary.

Interactions with other medicinal products and other forms of interaction

Heparin given in clinical dose causes a transient release of lipoprotein lipase into the circulation. This may result initially in increased plasma lipolysis followed by a transient decrease in triglyceride clearance.

Other drugs, such as insulin, may influence lipase activity but there us no evidence to suggest that this adversely effects therapeutic value.

Soybean oil has natural content of Vitamin K, which could effect coagulation particularly in patient receiving coumarine derivates. In practice this is uncommon but close monitoring of coagulation is advised for patients receiving these drugs.

There are no clinical data to show that any of the above mentioned interactions are of definite clinical relevance.

Incompatibilities

Kabiven Peripheral may only be mixed with other medicinal products for which compatibility has been documented. See instructions for use/ handling.

SHELF LIFE

2 years in the overpouch.

SHELF LIFE AFTER MIXING

After breaking the seals, chemical and physical in – use stability of the mixed three chamber bag has been demonstrated for 24 hours at 25°C.

STORAGE

Do not store above 25°C. Store in overpouch. Do not freeze.

AFTER MIXING WITH ADDITIVES

After opening the peelable seals and mixing of the three solutions, additions can be made via medication port.
From a microbiological point of view the product should be used immediately when addition have been made. If not used immediately, the in – use storage time and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2-8°C. If storage can not be avoided and provided that additions are made under controlled and validated aseptic conditions the mixed emulsion may be stored up to 6 days at 2-8°C before being used. After removal from storage at 2-8°C, the admixture should be infused within 24 hours.

INSTRUCTION FOR USE AND HANDLING

For single use only

Do not use if package is damaged. The contents of the three separate chambers have to be mixed before use.

After separation of the peelable seals the bag should be inverted on a number of occasions to ensure a homogenous mixture.

Use only if the amino acids and glucose solutions are clear and colourless of slightly yellow and if the fat emulsion is white and homogenous.

COMPATIBILITY

Additives
Only medicinal or nutritional solutions for which compatibility has been documented may be added to Kabiven Peripheral.

Addition should be made aseptically.

Mixing data are delivered upon request.

Any mixture remaining after infusion must be discarded.

PACKAGING :

Three chamber bag 1440 ml Reg No. DKI1274502049A1
Three chamber bag 1920 ml Reg No. DKI1274502049A1

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

Manufactured by :
Fresenius Kabi AB
75174 Uppsala, Sweden

Imported by :
PT. Fresenius Kabi Combiphar
Bandung - Indonesia

FRESENIUS KABI

335 315

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