Direction for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

NuTRIflex® Lipid special

Emulsion for infusion

Amino Acids + Glucose + Lipid

Especially suitable for infusion into central vein

Composition:
The ready to use emulsion for infusion contains after mixing of the contents of the individual chambers:

Active ingredients

– from the upper, left chamber	**in 625 ml**	**in 1250 ml**
Glucose monohydrate	99.0 g	198.0 g
equivalent to anhydrous glucose	90.0 g	180.0 g
Sodium dihydrogen phosphate dihydrate	1.56 g	3.120 g
Zinc acetate dihydrate	4.39 mg	8.78 mg

– from the upper, right chamber	**in 625 ml**	**in 1250 ml**
Soya-bean oil	12.5 g	25.0 g
Medium-chain triglycerides	12.5 g	25.0 g

– from the lower chamber	**in 625 ml**	**in 1250 ml**
Isoleucine	2.06 g	4.11 g
Leucine	2.74 g	5.48 g
Lysine hydrochloride	2.49 g	4.98 g
equivalent to Lysine	1.99 g	3.98 g
Methionine	1.71 g	3.42 g
Phenylalanine	3.08 g	6.15 g
Threonine	1.59 g	3.18 g
Tryptophan	0.50 g	1.00 g
Valine	2.26 g	4.51 g
Arginine	2.37 g	4.73 g
Histidine hydrochloride monohydrate	1.48 g	2.96 g
equivalent to Histidine	1.10 g	2.19 g
Alanine	4.25 g	8.49 g
Aspartic acid	1.32 g	2.63 g
Glutamic acid	3.07 g	6.14 g
Glycine	1.45 g	2.89 g
Proline	2.98 g	5.95 g
Serine	2.63 g	5.25 g
Sodium hydroxide	0.732 g	1.464 g
Sodium chloride	0.237 g	0.473 g
Sodium acetate trihydrate	0.157 g	0.313 g
Potassium acetate	2.306 g	4.611 g
Magnesium acetate tetrahydrate	0.569 g	1.137 g
Calcium chloride dihydrate	0.390 g	0.779 g

		in 625 ml	**in 1250 ml**
Amino acid content	[g]	35.9	71.8
Total nitrogen content	[g]	5	10
Carbohydrate content	[g]	90	180
Lipid content	[g]	25	50

		in 625 ml	**in 1250 ml**
Energy in the form of lipid	[kJ (kcal)]	995 (240)	1990 (475)
Energy in the form of carbohydrate	[kJ (kcal)]	1510 (360)	3015 (720)
Energy in the form of amino acids	[kJ (kcal)]	585 (140)	1170 (280)
Non-protein energy	[kJ (kcal)]	2505 (600)	5005 (1195)
Total energy	[kJ (kcal)]	3090 (740)	6175 (1475)
Osmolality (mOsm/kg)	2090		
pH	5.0 – 6.0		

Electrolytes (mmol)		
Sodium	33.5	67
Potassium	23.5	47
Magnesium	2.65	5.3
Calcium	2.65	5.3
Zinc	0.02	0.04
Chloride	30	60
Acetate	30	60
Phosphate	10	20

Excipients:
Citric acid monohydrate, egg lecithin, glycerol, sodium oleate, water for injections

Pharmaceutical form:
Emulsion for intravenous infusion in three-chamber bags containing 625 ml and 1250 ml

Pharmaco-therapeutic group:
Emulsion for intravenous supply of amino acids, carbohydrates, fat and electrolytes.

Indications:
Supply of energy, essential fatty acids, amino acids, electrolytes and fluids during parenteral nutrition for patients with mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.

Contraindications:
This product must not be administered in the following conditions
- disturbances of amino acid metabolism,
- disturbances of lipid metabolism,
- hyperkalaemia; hypernatraemia,
- unstable metabolism (e.g. severe postaggression syndrome, unstabilized diabetic metabolic situation, coma of unknown origin),
- hyperglycaemia not responding to insulin doses of up to 6 units insulin/hour,
- acidosis,
- intrahepatic cholestasis,
- severe hepatic insufficiency,
- severe renal insufficiency,
- manifest cardiac insufficiency,
- aggravating haemorrhagic diatheses,
- acute phases of cardiac infarction and stroke,
- acute event of thrombo-embolism, lipid embolism,
- known hypersensitivity to egg or soya-bean protein, peanut oil or to any of the excipients.

On account of its composition NuTRIflex Lipid special should not be used for neonates, infants and children under 2 years of age.
General contraindications to parenteral nutrition are:
- unstable circulatory status with vital threat (states of collapse and shock),
- inadequate cellular oxygen supply,
- states of hyperhydration,
- disturbances of the electrolyte and fluid balance,
- acute pulmonary oedema, decompensated cardiac insufficiency.

Special warnings and special precautions for use:
Due to the individual needs of paediatric patients, NuTRIflex Lipid special may not cover sufficiently the total energy requirements. In such cases carbohydrates and / or lipids must be provided in addition, as appropriate.

Caution should be exercised in cases of increased serum osmolarity

As for all large-volume infusion solutions NuTRIflex Lipid special should be administered with caution to patients with impaired cardiac or renal function. Disturbances of the fluid, electrolyte or acid-base balance, e.g. hyperhydration, hyperkalaemia, acidosis, should be corrected before the start of infusion. Too rapid infusion can lead to fluid overload with pathological serum electrolyte concentrations, hyperhydration and pulmonary oedema.

The serum triglyceride concentration should be monitored when infusing NuTRIflex® Lipid special. Fasting lipaemia should be excluded in patients with suspected disturbances of lipid metabolism before starting infusion. The administration of lipids is contraindicated if there is fasting lipaemia. The presence of hypertriglyceridaemia 12 hours after lipid administration also indicates a disturbance of lipid metabolism.

NuTRIflex Lipid special should be administered cautiously to patients with disturbances of lipid metabolism, e.g. renal insufficiency, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (with hypertriglyceridemia) and sepsis. If NuTRIflex Lipid special is given to patients with these conditions, close monitoring of serum triglycerides is mandatory.

Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

Depending on the patient's metabolic condition, occasional hypertriglyceridaemia or increases of the blood glucose concentration may occur. If the plasma triglyceride concentration rises to more than 3 mmol/l during administration of lipid it is recommended that the infusion rate should be reduced. Should the plasma triglyceride concentration remain above 3 mmol/l the administration should be stopped until the level normalizes.

A dose reduction or interruption of administration is also indicated if the blood glucose concentration rises to more than 14 mmol/l (250 mg/dl) when administering the product.

As with all solutions containing carbohydrates the administration of NuTRIflex Lipid special can lead to hyperglycaemia. The blood glucose level should be monitored. If there is hyperglycaemia the rate of infusion should be reduced or insulin should be administered.

Intravenous infusion of amino acids is accompanied by increased urinary excretion of the trace elements, especially copper and, in particular, zinc. This should be considered in the dosing of trace elements, especially during long-term intravenous nutrition.

NuTRIflex Lipid special should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.

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Moreover controls of the serum electrolytes, the water balance, the acid-base balance and – during long-term administration - of blood cell counts, coagulation status and hepatic function are necessary.

The fat content may interfere with certain laboratory measurements (e.g. bilirubin, lactate dehydrogenase, oxygen saturation). if blood is sampled before fat has been adequately cleared from the blood stream.

Substitution of electrolytes, vitamins and trace elements may be necessary as required.

As NuTRIflex Lipid special contains zinc and magnesium, care should be taken when it is co-administered with solutions containing these elements.

As with all intravenous solutions strict aseptic precautions are necessary for the infusion of NuTRIflex® Lipid special.

NuTRIflex Lipid special is a preparation of complex composition. It is, therefore, strongly advisable not to add other solutions.

Pregnancy and lactation:
Preclinical studies have not been performed with NuTRIflex Lipid special. The prescriber should consider the benefit/ risk relationship before administering NuTRIflex Lipid special to pregnant women.
Breast-feeding is not recommended if women need parenteral nutrition in that time.

Interactions:
Some drugs, like insulin, may interfere with the body's lipase system. This kind of interaction seems, however, to be of only limited clinical importance.

Heparin given in clinical doses 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.

Soya-bean oil has a natural content of vitamin K_1. This may interfere with the therapeutic effect of coumarin derivatives which should be closely monitored in patients treated with such drugs.

Dosage:
The dosage is adjusted according to the patients' individual requirements.

Adults:
The maximum daily dose is 35 ml/kg body weight, corresponding to
– 2.0 g amino acids /kg body weight per day,
– 5.04 g glucose /kg body weight per day,
– 1.4 g lipid /kg body weight per day.

It is recommended that NuTRIflex® Lipid special be administered continuously. A stepwise increase of the infusion rate over the first 30 minutes up to the desired infusion rate helps to avoid complications.

The maximum rate of infusion is 1.7 ml/kg body weight per hour, corresponding to
– 0.1 g amino acids /kg body weight per hour,
– 0.24 g glucose /kg body weight per hour,
– 0.07 g lipid /kg body weight per hour.

For a patient weighing 70 kg this corresponds to an infusion rate of 119 ml/kg body weight per hour. The amount of amino acid administered is then 6.8 g/hour, of glucose 17.1 g/hour and of lipid 4.8 g/hour.

In general, it is recommended that the maximum amount of energy should not exceed 40 kcal/kg BW and day. If specially indicated e.g. for burned patients higher dosage is possible.

Children over 2 years of age:
The given dosage recommendations are guiding data based on average requirements. The dosage should be individually adapted, according to age, development stage and illness. For calculation of dosage account must be taken of the hydration status of the paediatric patient.

For children, it might be necessary to start the nutritional therapy with half of the target dosage. The dosage should be increased stepwise according to the individual metabolic capacity up the maximum dosage.

Daily dose during 3rd – 5th year of life:
25 ml/kg body weight, corresponding to
– 1.43 g amino acids/kg body weight per day
– 3.60 g glucose /kg body weight per day
– 1,0 g lipid /kg body weight per day.

Daily dose during 6th – 14th year of life:
17,5 ml/kg body weight, corresponding to
– 1.0 g amino acids/kg body weight per day
– 2.52 g glucose /kg body weight per day
– 0.7 g lipid /kg body weight per day.

The maximum rate of infusion is 1.7 ml/kg body weight per hour, corresponding to
– 0.1 g amino acids/kg body weight per hour
– 0.24 g glucose /kg body weight per hour
– 0.07 g lipid /kg body weight per hour.

Additional energy that may be required for paediatric patients should be administered in the form of glucose solutions or fat emulsions, as appropriate.

Method of administration
For central venous infusion only

Preparation of the mixed solution:
Remove the bag from its protective pack and proceed as follows:
- open out the bag and lay on a solid surface
- open the peel seals to the two upper chambers by using pressure with both hands
- briefly mix the contents of the bag together

Preparation for infusion:
- fold the two empty chambers backwards
- hang the mixing bag on the infusion stand by the centre hanging loop
- remove the protective cap from the run-out port and carry out infusion using the normal technique

Duration of use
The duration of treatment for the indications stated is not limited. During long-term administration of NuTRIflex® Lipid special it is necessary to supply appropriate replacement of trace elements and vitamins.

Overdose
Overdose of NuTRIflex Lipid special is not to be expected on proper administration.

Symptoms of fluid and electrolyte overdose
Hypertonic hyperhydration, electrolyte imbalance and pulmonary oedema.

Symptoms of amino acid overdose:
Renal amino acid losses with consecutive amino acid imbalances, sickness, vomiting and shivering.

Symptoms of glucose overdose:
Hyperglycaemia, glucosuria, dehydration, hyperosmolality, hyperglycaemic and hyperosmolar coma.

Symptoms of lipid overdose:
Lipid overdose may lead to the overload syndrome, characterised (for example) by fever, headache, abdominal pain, fatigue, hyperlipaemia, hepatomegaly with or without jaundice, splenomegaly, pathological disturbances of liver function, anaemia, reduction in platelet count, reduction in white cell count, haemorrhagic diathesis and haemorrhage, alteration or depression of blood coagulation factors (bleeding time, coagulation time, prothrombin time etc.). The plasma triglyceride concentration should not exceed 3 mmol/l during infusion.

Emergency treatment, antidotes
Immediate stop of infusion is indicated in the case of overdose. Further therapeutic measures depend on the particular symptoms and their severity. When infusion is recommenced after the symptoms have declined it is recommended that the infusion rate be raised gradually with monitoring at frequent intervals.

Undesirable effects:
Possible early reactions on the administration of lipid emulsions are: slight increase in temperature, flush, cold feeling, shivering, loss of appetite, nausea, vomiting, respiratory distress, headache, backache, bone pain, pain in the chest and lumbar region, fall or increase in blood pressure (hypotension, hypertension), hypersensitivity reactions (e.g. anaphylactic reactions, dermal eruptions).
Hot flushes or bluish discoloration of the skin due to reduced oxygen content of the blood (cyanosis) can occur as side effects.
If these side effects occur the infusion should be discontinued or, if appropriate, the infusion should be continued at a lower dose level.
Attention should be paid to the possibility of an overloading syndrome This can occur as a result of individually varying, genetically determined metabolic conditions and can occur at different rates and after differing doses depending on previous disorders. Overloading syndrome is associated with the following symptoms: enlargement of the liver (hepatomegaly) with or without jaundice (icterus), enlargement of the spleen (splenomegaly), fatty infiltration of organs, pathological hepatic function parameters, anaemia, reduction of white cell count (leucopenia), reduction of platelet count (thrombocytopenia), a tendency to haemorrhage and haemorrhages, alterations or reduction in the blood coagulation factors (bleeding time, coagulation time, prothrombin time etc.), fever, hyperlipaemia, headache, stomach-ache, fatigue.
Please inform your doctor or pharmacist if you notice any undesirable effect that is not mentioned in this leaflet.

Instructions for storage / use / handling:
Do not use the product beyond the expiry date stated on the labelling.

The ready-to-use emulsion can be stored for 4 days at 2 – 8 °C plus 48 hours at 25 °C.

The emulsion is to be used immediately after connecting the container to the giving set.

NuTRIflex Lipid special is supplied in single dose containers. Unused residues must be discarded.

If filters are used they must be lipid-permeable.

Do not store above 25 °C.

Do not freeze. If accidentally frozen, discard the bag.

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

Only use bags that are undamaged and in which the amino acid and glucose solutions are clear. Do not use bags where there is discernible phase separation (oil drops) in the chamber containing lipid emulsion.

Presentation : NuTRIflex Lipid Special 625 ml, 1250 ml
3 chamber compartment bag

Reg No : DKI 1286701449A1

Harus dengan resep dokter

Licence Holder : **PT. Phapros Tbk.,** Indonesia

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Imported by : **PT. B.Braun Medical Indonesia**
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