Professional Information

SCHEDULING STATUS:

S3

1. NAME OF THE MEDICINE

NUTRIFLEX® LIPID PERI (Intravenous infusion)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The ready for use infusion contains after mixing the chamber contents:

COMPOSITION			
	In 1250 mL	**In 1875 mL**	**In 2500 mL**
From upper left compartment (glucose solution)			
Glucose monohydrate *equivalent to glucose*	88,0 g 80,0 g	132,0 g 120,0 g	176,0 g 160,0 g
Sodium dihydrogen phosphate dihydrate	1,170 g	1,755 g	2,340 g
Zinc acetate dihydrate	6,625 mg	9,90 mg	13,20 mg
From upper right compartment (fat emulsion)			
Medium chain triglycerides	25,00 g	37,50 g	50,00 g
Soya-bean oil, refined	25,00 g	37, 50 g	50,00 g
From lower compartment (amino acid solution)			
Isoleucine	2,34 g	3,51 g	4,68 g

Leucine	3,13 g	4,70 g	6,26 g
Lysine hydrochloride *equivalent to lysine*	2,84 g 2,26 g	4,26 g 3,39 g	5,68 g 4,52 g
Methionine	1,96 g	2,94 g	3,92 g
Phenylalanine	3,51 g	5,27 g	7,02 g
Threonine	1,82 g	2,73 g	3,64 g
Tryptophan	0,57 g	0,86 g	1,14 g
Valine	2,60 g	3,90 g	5,20 g
Arginine	2,70 g	4,05 g	5,40 g
Histidine hydrochloride monohydrate *equivalent to histidine*	1,69 g 1,25 g	2,54 g 1,88 g	3,38 g 2,50 g
Alanine	4,85 g	7,28 g	9,70 g
Aspartic acid	1,50 g	2,25 g	3,00 g
Glutamic acid	3,50 g	5,25 g	7,00 g
Glycine	1,65 g	2,48 g	3,30 g
Proline	3,40 g	5,10 g	6,80 g
Serine	3,00 g	4,50 g	6,00 g
Sodium hydroxide	0,80 g	1,20 g	1,60 g
Sodium chloride	1,081 g	1,622 g	2,162 g
Sodium acetate trihydrate	0,544 g	0,816 g	1,088 g
Potassium acetate	2,943 g	4,415 g	5,886 g
Magnesium acetate tetrahydrate	0,644 g	0,966 g	1,288 g
Calcium chloride dihydrate	0,441 g	0,662 g	0,882 g
Amino acid content	40,0 g	60,0 g	80,0 g
Total Nitrogen content	5,7 g	8,6 g	11,4 g

Carbohydrate content	80,0 g	120,0 g	160,0 g
Lipid content	50,0 g	75,0 g	100,0 g
Electrolyte content (mmol)			
Sodium	50	70	100
Potassium	30	45	60
Magnesium	3,0	4,5	6,0
Calcium	3,0	4,5	6,0
Zinc	0,03	0,045	0,06
Chloride	48	72	96
Acetate	40	60	80
Phosphate	7,5	11,25	15

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intravenous infusion

Amino acid chamber: Clear, colourless up to faintly straw coloured solution

Glucose chamber: Clear, colourless up to faintly straw coloured solution

Fat emulsion chamber: A white, milky oil-in-water emulsion.

	In 1250 mL	In 1875 mL	In 2500 mL
Energy in the form of lipid [kJ/(kcal)]	1990 (475)	2985 (715)	3980 (950)
Energy in the form of carbohydrate [kJ/(kcal)]	1340 (320)	2010 (480)	2680 (640)
Energy in the form of amino acids [kJ/(kcal)]	670 (160)	1005 (240)	1340 (320)
Non-protein energy [kJ/(kcal)]	3330 (795)	4995 (1195)	6660 (1590)
Total energy [kJ/(kcal)]	4000 (955)	6000 (1435)	8000 (1910)
Osmolality [mOsm/kg]	920	920	920
Theoretical osmolarity [mOsm/L]	840	840	840
pH	5,0 – 6,0	5,0 – 6,0	5,0 – 6,0

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Supply of the daily requirement 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.

4.2 Posology and method of administration

Posology

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

The maximum daily dose is 40 mL/kg body weight, corresponding to:

- 1,28 g amino acids /kg body weight per day
- 2,56 g glucose /kg body weight per day
- 1,6 g fat /kg body weight per day

It is recommended that **Nutriflex® Lipid Peri** be administered continuously. A stepwise increase of the infusion rate over the first 30 minutes up to the desired infusion rate avoids possible complications.

The maximum rate of infusion is 2,5 mL/kg body weight per hour, corresponding to

- 0,08 g amino acids / kg body weight per hour
- 0,16 g glucose / kg body weight per hour
- 0,1 g fat / kg body weight per hour

For a patient weighing 70 kg this corresponds to an infusion rate of 175 mL per hour. The amount of amino acid administered is then 5,6 g/hour, of glucose 11,2 g/hour and of lipid 7,0 g/hour.

Method of administration

For intravenous infusion. Especially suitable for infusion into peripheral veins.

Duration of treatment

The duration of treatment for the indications stated should not exceed 7 days.

Refer to section 6.6 for details of handling and preparation.

4.3 Contraindications

This product must not be administered in the following conditions:

- Hypersensitivity to the active substances, to egg, peanut or soya protein or to any of the

excipients listed in section 6.1

- Disturbances of amino acid metabolism
- Disturbances of lipid metabolism
- Hypokalaemia; hyponatraemia
- Unstable metabolism e.g. severe post aggression syndrome (an endocrine imbalance with glucose intolerance and peripheral resistance to insulin, which can result in persistent hyperglycaemic states with increased lipolysis and progressive proteolysis), unstabilised diabetes mellitus 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 myocardial infarction and stroke
- Acute event of thromboembolism, lipid embolism

On account of its composition **Nutriflex® Lipid Peri** should not be used for neonates, infants and children under 2 years of age.

General contra-indications to parenteral nutrition are:

- Unstable circulatory status

- Inadequate cellular oxygen supply

- Fluid overload/overhydration

- Disturbances of the electrolyte and fluid balance

- Acute pulmonary oedema, decompensated cardiac insufficiency

4.4 Special warnings and precautions for use

Caution should be exercised in cases of increased serum osmolarity.

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.

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

The serum triglyceride concentration should be monitored when infusing **Nutriflex® Lipid Peri**. 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.

Patients with impaired lipid metabolism

Nutriflex® Lipid Peri should be administered cautiously to patient with disturbances of lipid metabolism, e.g. renal insufficiency, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (with hypertriglyceridaemia), and sepsis. If **Nutriflex® Lipid Peri** is given to patients with these conditions, more frequent monitoring of serum triglycerides is mandatory.

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.

The administration of **Nutriflex® Lipid Peri** 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. If the patient is receiving other intravenous glucose solutions concurrently, the amount of additionally administered glucose has to be taken into account. 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 lipid.

Refeeding or repletion of malnourished or depleted patients may cause hypokalaemia, hypophosphataemia and hypomagnesaemia. Adequate supplementation of electrolytes according to deviations from normal values is necessary.
Controls of the serum electrolytes, the water balance, acid-base balance, and of blood cell counts, coagulation status, renal and hepatic function are necessary.

Substitution of electrolytes, vitamins and trace elements may be necessary as required. As **Nutriflex® Lipid Peri** contains zinc, magnesium, calcium and phosphate, care should be taken when it is co-administered with solutions containing these elements.

Nutriflex® Lipid Peri should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination (see also section 4.5).

Nutriflex® Lipid Peri is a preparation of complex composition. It is, therefore, strongly advisable not to add other solutions (as long as compatibility is not proven – see section 6.2).

As with all intravenous solutions, especially for parenteral nutrition, strict aseptic precautions are necessary for the infusion of **Nutriflex® Lipid Peri**.

Additions can increase the overall osmolarity of the emulsion, consider with regard to peripheral administration and monitor the injection site.

Infusion in peripheral veins may cause thrombophlebitis. Monitor infusion site daily for signs of thrombophlebitis.

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.

Patients with diabetes mellitus or renal function

Like all large-volume infusion solutions, **Nutriflex® Lipid Peri** should be administered with caution to patients with impaired renal function.

There is only limited experience of its use in patients with diabetes mellitus or renal failure.

***Nutriflex® Lipid Peri** contains sodium*

This medicinal product contains 1150 mg sodium per 1250 mL bag, equivalent to 58 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

The maximum daily dose of this product for a 70 kg adult is equivalent to 129 % of the WHO recommended maximum daily intake for sodium.

Nutriflex® Lipid Peri is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

Interference with laboratory tests:

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.

4.5 Interaction with other medicinal products and other forms of interaction

Some medication, 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 agents.

Potassium-containing solutions like **Nutriflex® Lipid Peri** should be used with caution in patients receiving drugs that increase serum potassium concentration, such as potassium-sparing diuretics (triamterene, amiloride, spironolactone), ACE inhibitors (e.g. captopril, enalapril), angiotensin-II-receptor antagonists (e.g. losartan, valsartan), ciclosporin and tacrolimus.

Corticosteroids and ACTH are associated with sodium and fluid retention.

Nutriflex® Lipid Peri should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination (see also section 4.4).

Solutions containing amino acids, carbohydrate and lipids should not be mixed with other

solutions due to the risk for incompatibilities or microbial contamination. Concomitant infusion with other medicines should also be avoided due to the risk of incompatibilities (see section 6.2).

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and efficacy have not yet been established.

Lactation

Breastfeeding is not recommended if women need parenteral nutrition.

Fertility

Nutriflex® Lipid Peri is manufactured with soy-bean oil that contains phytosterols in concentrations that could lead to disturbances of fertility.

4.7 Effects on ability to drive and use machines

Nutriflex® Lipid Peri has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Under conditions of correct use, in terms of dosing monitoring, observation of safety restrictions and instructions, undesirable effects may still occur. The following listing includes a number of systemic reactions that may be associated with the use of **Nutriflex® Lipid Peri**.

Blood and lymphatic system disorders:

Less frequent: Hypercoagulation.

Frequency unknown: Hypokalaemia, hypophosphataemia, hypomagnesaemia, hypermagnesaemia, leucopenia, thrombocytopenia.

Immune system disorders:

Less frequent: Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema).

Metabolism and nutrition disorders:

Less frequent: Loss of appetite, hyperlipidaemia, hyperglycaemia, metabolic acidosis.

The frequency of these undesirable effects is dose-dependent and may be higher under the condition of absolute or relative lipid overdose.

Nervous system disorders:

Less frequent: Headache, drowsiness.

Vascular disorders:

Less frequent: Hypertension or hypotension, flush.

Respiratory, thoracic and mediastinal disorders:

Less frequent: Dyspnoea, cyanosis.

Frequency unknown: Respiratory distress.

Gastrointestinal disorders:

Less frequent: Nausea, vomiting.

Hepatobiliary disorders:

Frequency unknown: Cholestasis.

Skin and subcutaneous tissue disorders:

Less frequent: Erythema, sweating

Frequency unknown: Bluish discoloration of the skin due to reduced oxygen content of the blood (cyanosis).

Musculoskeletal and connective tissue disorders:

Less frequent: Back ache, pain in the chest, bones and lumbar region.

Cardiac disorders:

Frequency unknown: Fall or increase in blood pressure.

General disorders and administration site conditions:

Frequent: After a few days, vein irritation, phlebitis or thrombophlebitis may occur.

Less frequent: Elevated body temperature, feeling cold, chills, Fat overload syndrome (see below for details).

Frequency unknown: Infection of the injection site which can lead to septicaemia; irritation at the injection site.

If signs of vein wall irritation, phlebitis, or thrombophlebitis occur, change of the infusion site should be considered.

If any of the above mentioned side-effects occur the infusion should be discontinued or, if appropriate, the infusion should be continued at a lower dose level.

Should the triglyceride level rise to above 11,4 mmol/L (1000 mg/dL) during infusion, the infusion must be stopped. With levels above 4,6 mmol/L (400 mg/dL), the infusion may be continued at a reduced dosage (see section 4.4).

If the infusion is restarted, the patient should be carefully monitored, especially at the beginning, and serum triglycerides should be determined at short intervals.

Information on particular undesirable effects

Nausea, vomiting and lack of appetite are symptoms often related to conditions for which parenteral nutrition is indicated and may be associated with parenteral nutrition at the same time.

Fat overload syndrome

Impaired capacity to eliminate triglycerides can lead to ‘fat overload syndrome’, which may be caused by overdose. Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolism) or the fat metabolism may be affected by ongoing or previous illnesses. This syndrome may also appear during severe hypertriglyceridaemia, even at the recommended infusion rate, and in association with a sudden change in the patient’s clinical condition such as renal function impairment or infection. The fat overload syndrome is characterised by hyperlipidaemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anaemia, leucopenia, thrombocytopenia, coagulation disorder, haemolysis and reticulocytosis, abnormal liver function tests and coma. The symptoms are usually reversible if the infusion of the fat emulsion is discontinued.

Should signs of a fat overload syndrome occur, the infusion of **Nutriflex® Lipid Peri** should be discontinued immediately.

4.9 Overdose

Overdose of **Nutriflex® Lipid Peri** 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, glycosuria, 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 if platelet count, reduction in white cell count, hemorrhagic diathesis and haemorrhage, alternation of depression of blood coagulation factors (bleeding time, coagulation time, prothrombin time, etc.). The plasma triglyceride concentration should not exceed 3 mmol/L during infusion.

Refer to section 4.8.

Treatment

Immediate cessation 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A. 25 Special Foods

Pharmacotherapeutic group: Solutions for parenteral nutrition, combinations

ATC code: B 05BA10

Mechanism of action

The purpose of parenteral nutrition is to supply all necessary nutrients and energy for the growth and/or regeneration of tissue as well as for the maintenance of all body functions.

Lipids

The lipid component of **Nutriflex® Lipid Peri** contains equal quantities of soybean oil (long-chain triglycerides, LCT) and medium-chain triglycerides (MCT). Soybean oil consists of more than 50 % of the polyunsaturated fatty acids linoleic acid and α-linolenic acid. MCT are included as a high calorie source.

On account of their high energy density, lipids are an efficient form of energy supply. Long-chain triglycerides provide the organism with essential fatty acids for the synthesis of cell components. For these purposes the fat emulsion contains medium-chain and long-chain triglycerides (deriving from soya-bean oil).

Medium-chain triglycerides are more rapidly hydrolysed, eliminated from the circulation and completely oxidised than long-chain triglycerides. They are a favoured energy substrate, particularly when there is disturbance of the degradation and/or utilisation of long-chain triglycerides, e.g. when there is a lipoprotein lipase deficiency and/or a deficiency in lipoprotein lipase cofactors.

Unsaturated fatty acids derived from the long-chain triglyceride fraction serve primarily for prophylaxis and treatment of essential fatty acid deficiency.

Carbohydrates

In order to ensure optimal utilization of the amino acids delivered with the nutrient solution, and to

improve the emulsion triglyceride utilization, an energy source is required. This can be partly fulfilled by carbohydrates namely glucose monohydrate.
Glucose is ubiquitously metabolised within the organism. Some tissues and organs, such as CNS, bone marrow, erythrocytes, tubular epithelium, cover their energy requirement exclusively from glucose. In addition glucose acts as a structural building block for various cell substances.

Amino acids

Nutriflex® Lipid Peri contains all essential amino acids and the non-essential amino acids. Amino acids are of particular importance since some of them are essential components for protein synthesis. The simultaneous administration of energy sources (carbohydrates/lipids) is necessary to reserve amino acids for tissue regeneration and anabolism and prevent their utilisation as energy source.

Electrolytes

Nutriflex® Lipid Peri contains all the essential electrolytes, i.e. sodium, potassium, magnesium, calcium and phosphate. It also contains the trace element zinc.

5.2 Pharmacokinetic properties

Absorption

Nutriflex® Lipid Peri is infused intravenously. Hence, all substrates are available for metabolism immediately.

Distribution

The dose, rate of infusion, metabolic situation and individual factors of the patient (level of fasting) are of decisive importance for the maximum triglyceride concentrations reached. When used according to the instructions with due regard to the dosage guidelines the triglyceride

concentrations do not, in general, exceed 4,6 mmol/L (400 mg/dL).

Medium-chain fatty acids have a low affinity to albumin. In animal experiments administering pure medium-chain triglyceride emulsions, it has been shown that medium-chain fatty acids can cross the blood-brain barrier, if overdosed. No adverse effects were observed with an emulsion providing a mixture of medium-chain triglycerides and long-chain triglycerides, as long-chain triglycerides have an inhibiting effect on medium-chain triglyceride hydrolysis. Therefore, toxic effects on the brain can be excluded after the administration of **Nutriflex® Lipid Peri**.

Amino acids are incorporated in a variety of proteins in different organs of the body. In addition each amino acid is maintained as free amino acid in the blood and inside cells.

As glucose is water-soluble, it is distributed with the blood over the whole body. At first, the glucose solution is distributed in the intravascular space and then it is taken up into the intracellular space.

No data are available concerning transport of the components through the placental barrier.

Biotransformation

Amino acids that do not enter protein synthesis are metabolised as follows. The amino group is separated from the carbon skeleton by transamination. The carbon chain is either oxidised directly to CO_2 or utilised as substrate for gluconeogenesis in the liver. The amino group is also metabolised in the liver to urea.

Glucose is metabolised to CO_2 and H_2O via the known metabolic routes. Some glucose is utilised for lipid synthesis.

After infusion, triglycerides are hydrolysed to glycerol and fatty acids. Both are incorporated in physiological pathways for energy production, synthesis of biological active molecules, gluconeogenesis and resynthesis of lipids.

Elimination

Only minor amounts of amino acids are excreted unchanged in urine.

Excess glucose is excreted in urine only if the renal threshold of glucose is reached.

Both the triglycerides of soya-bean oil and medium-chain triglycerides are completely metabolised to CO_2 and H_2O. Small amounts of lipids are lost only during sloughing of cells from skin and other epithelial membranes. Renal excretion does virtually not occur.

5.3 Preclinical safety data

Non-clinical studies have not been performed with **Nutriflex® Lipid Peri**.

Toxic effects of mixtures of nutrients given as substitution therapy at the recommended dosage are not to be expected.

Reproductive toxicity

Phytoestrogens such as ß-sitosterol can be found in various vegetable oils, especially in soya-

bean oil. Impairment of fertility was determined in rats and rabbits after subcutaneous and intravaginal administration of ß-sitosterol. According to the current state of knowledge the observed effects in animals do not seem to have relevance for clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate (for pH adjustment)

Glycerol

Egg lecithin

Sodium oleate

Water for injections

6.2 Incompatibilities

Nutriflex® Lipid Peri must not be mixed with other medicinal products for which compatibility has not been documented. See section 6.6.

Nutriflex® Lipid Peri should not be given simultaneously with blood, see sections 4.4 and 4.5.

6.3 Shelf life

Unopened

2 years

After removing the protective overwrap and after mixing of contents of the bag

Chemical and physicochemical in-use stability of the mixture of amino acids, glucose and fat was demonstrated for 7 days at 2 - 8 °C and additional 2 days at 25 °C.

After admixture of compatible additives

From a microbiological point of view, the product should be used immediately after admixture of additives. If not used immediately after admixture of additives, in-use storage times and conditions prior to use are the responsibility of the user.

After first opening (spiking of the infusion port)

The emulsion is to be used immediately after opening of the container.

6.4 Special precautions for storage

Protect form light and store at or below 25 °C.

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

The emulsion is to be used immediately after mixing. It can be stored for 7 days at 2 - 8 °C and for 48 hours at 25 °C.

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

6.5 Nature and contents of container

Nutriflex Lipid Peri is manufactured as a transparent colourless three chamber bag. The two upper compartments of this bag are connected with the lower compartment by peel seams. The bag is made of a co-extruded film of Polyamide 11 and Polypropylene (V90 film)

Pack sizes: 5 x 1250 mL; 5 x 1875 mL; 5 x 2500 mL.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Parenteral nutrition products should be visually inspected for damage, discolouration and emulsion instability before use.

Do not use bags which are damaged. Overwrap, primary bag and the peel seams between the

chambers should be intact. Only use if the amino acid and glucose solutions are clear and colourless up to straw coloured and the lipid emulsion is homogenous with milky white appearance. Do not use if the solutions contain particulate matter. After mixing the three chambers, do not use if the emulsion shows discolouration or signs of phase separation (oil drops, oil layer). Stop the infusion immediately in case of discolouration of the emulsion or signs of phase separation.

Preparation of mixed solution

Remove the inner bag from its protective pack and proceed as follows:

- Open out the bag and lay on a solid surface
- Mix glucose with amino acids by pressing the upper left chamber against the peel seam, then add the fat emulsion by pressing the upper right chamber against the peel seam.
- Mix the contents of the bag thoroughly.

The mixture is a milky-white homogenous oil-in-water emulsion.

Preparation for infusion

The emulsion should always be brought to room temperature prior to 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

For single use only.

Container and unused residues must be discarded after use.

Do not reconnect partially used containers.

If filters are used they must be lipid-permeable (pore size ≥ 1,2 µm).

7. HOLDER OF CERTIFICATE OF REGISTRATION

B Braun Medical (Pty) Ltd

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8. REGISTRATION NUMBER:

41/25/0757

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11 February 2011

10. DATE OF REVISION OF THE TEXT

16 May 2023