B BRAUN
SHARING EXPERTISE

NEW

PRESCRIPTION | PATIENT ACCESS | PREPARATION | APPLICATION | DISCHARGE MANAGEMENT

Nutriflex® 3-Chamber Bags for Parenteral Nutrition

Bag evolution and extended portfolio

Bag Design

Clear – Practical – User friendly

Clear labeling

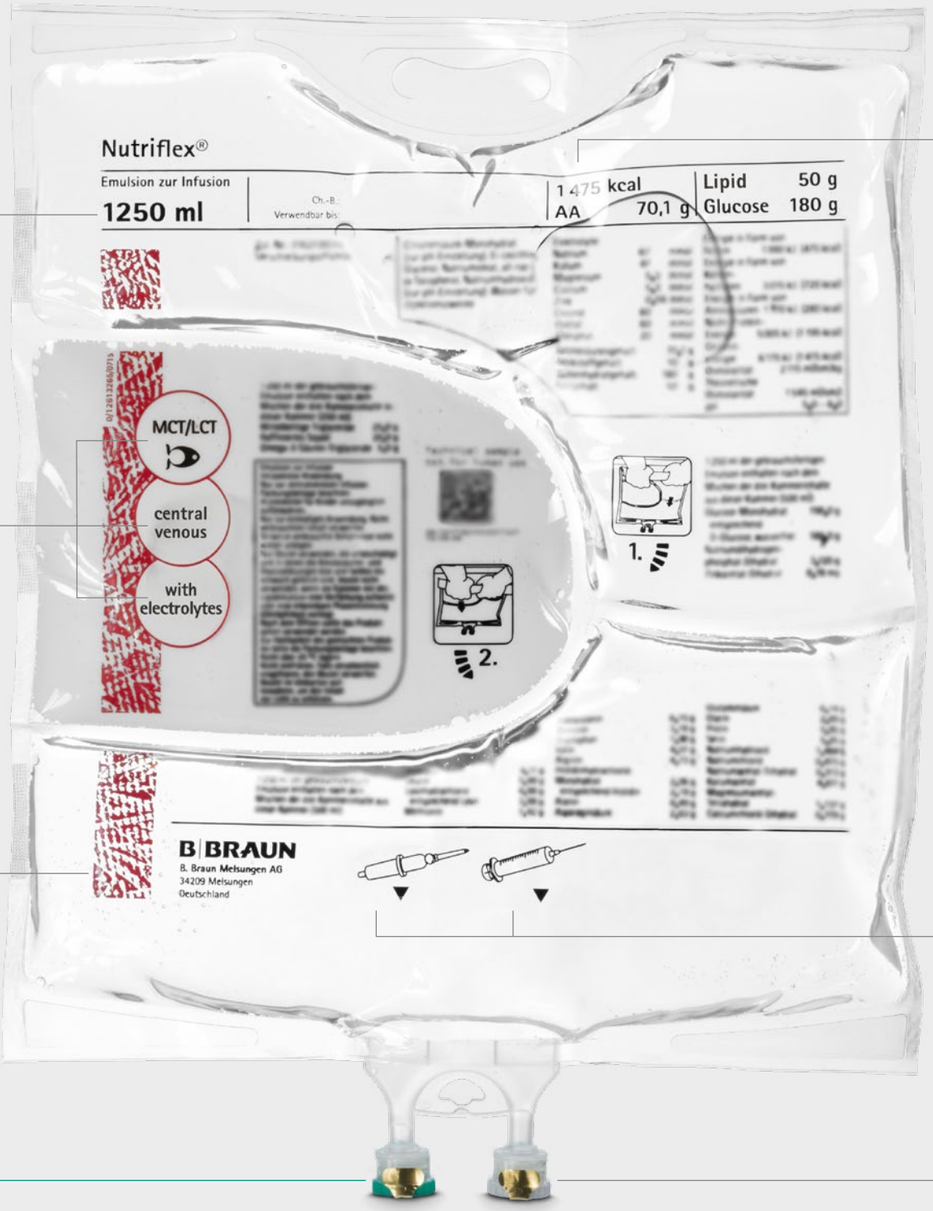
- Of the volume in ml

Quick reference for key information

- The lipid emulsion in the bag (Lipofundin® or Lipidem®/Lipoplus®)
- Administration route (peripheral or/and central venous)
- With or without electrolytes

Colour coordination for a better differentiation of the portfolio

- Blue/Peri Versions: 32 g/l amino acids, 64 g/l glucose
- Green/Plus Versions: 38 g/l amino acids, 120 g/l glucose
- Red/Special Versions: 56 g/l amino acids, 144 g/l glucose



Practical information

- List of macronutrient and caloric content

Advanced Port System with stabel, sterile ports

May reduce needle stick injuries

- Due to a bigger diameter and long port neck
- Easy-to-grip

User friendly

- Color coding: Different port colors clearly differentiate between the additive (white cap) and the infusion port (green cap)

Infusion port

Additive port

Infusion port

Additive port

Stable and sterile ports

Extended Product Range

All features at glance

Nutriflex® Lipid*

with Lipofundin® (MCT/LCT) as lipid component [1-4]

MEDIUM-CHAIN TRIGLYCERIDES
Source of rapid energy

SOYA BEAN OIL
Covers essential fatty acid requirements

Product	Color code	Bag sizes	Peripheral Venous	Central Venous	Electrolytes
Nutriflex® Lipid 32/64 peri* [1] 32 g/l amino acids 64 g/l glucose 40 g/l lipid		1,250 ml 1,875 ml 2,500 ml	■	■	■
Nutriflex® Lipid 38/120 plus* [2] 38 g/l amino acids 120 g/l glucose 40 g/l lipid		1,250 ml 1,875 ml 2,500 ml	–	■	■
Nutriflex® Lipid 56/144 special* [3] 56 g/l amino acids 144 g/l glucose 40 g/l lipid		625 ml 1,250 ml 1,875 ml	–	■	■
Nutriflex® Lipid 56/144 special without electrolytes* [4] 56 g/l amino acids 144 g/l glucose 40 g/l lipid		625 ml 1,250 ml 1,875 ml	–	■	–

* Not all versions and bag sizes are available in all countries. Names can differ from country to country.

Nutriflex® Omega*

with Lipidem®/Lipoplus®* (MCT/LCT/Omega-3-acid Triglycerides) as lipid component [5-8]

MEDIUM-CHAIN TRIGLYCERIDES
Source of rapid energy

SOYA BEAN OIL
Covers essential fatty acid requirements

OMEGA-3-ACID TRIGLYCERIDES
From fish oil

Product	Color code	Bag sizes	Peripheral Venous	Central Venous	Electrolytes
Nutriflex® Omega peri* [5] 32 g/l amino acids 64 g/l glucose 40 g/l lipids		1,250 ml 1,875 ml 2,500 ml	■	■	■
Nutriflex® Omega 38/120/40* [6] 38 g/l amino acids 120 g/l glucose 40 g/l lipids		1,250 ml 1,875 ml 2,500 ml	–	■	■
Nutriflex® Omega 56/144/40* [7] 56 g/l amino acids 144 g/l glucose 40 g/l lipids		625 ml 1,250 ml 1,875 ml	–	■	■
Nutriflex® Omega special without electrolytes* [8] 56 g/l amino acids 144 g/l glucose 40 g/l lipids		625 ml 1,250 ml 1,875 ml	–	■	–

*Not all versions and bag sizes are available in all countries. Names can differ from country to country.

Color coding

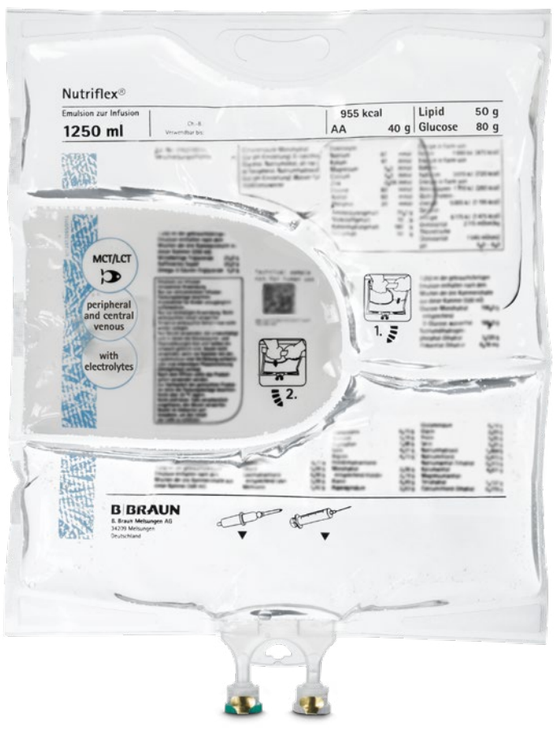
Blue – Green – Red

Color codes on the primary bag enables an easy differentiation of the different versions

WITHOUT ELECTROLYTES

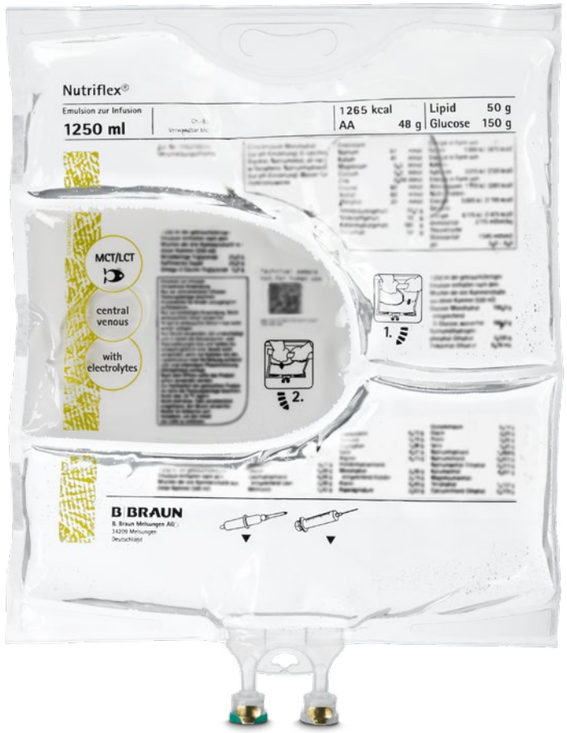
BLUE COLOR

32 g/l amino acids
64 g/l glucose
40 g/l lipid



GREEN COLOR

38 g/l amino acids
120 g/l glucose
40 g/l lipid

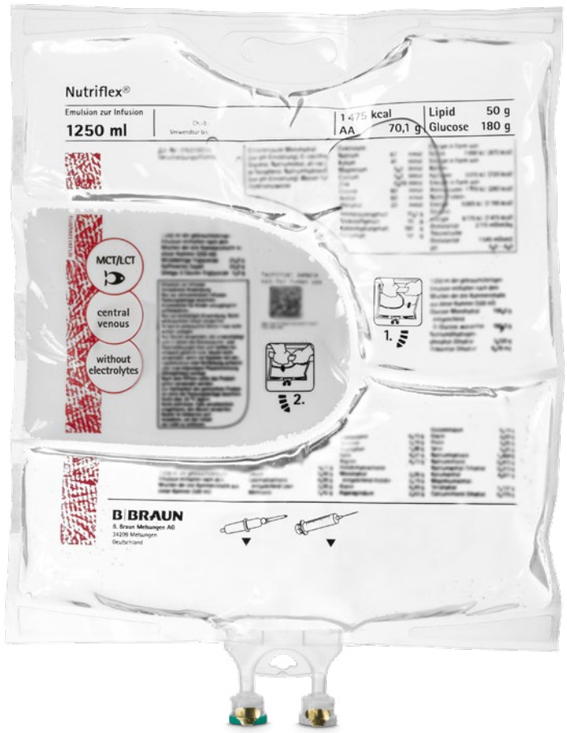


RED COLOR

56 g/l amino acids
144 g/l glucose
40 g/l lipid

RED COLOR

56 g/l amino acids
144 g/l glucose
40 g/l lipid



Mix – Ready – Infuse

Soft material easy to handle

1 PREPARATION

Tear overwrap starting from the tear notches at both sides.[1-8]

Remove the bag from its protective overwrap.[1-8]

Discard overwrap, oxygen indicator, and oxygen absorber.[1-8]

! Safety Aspect

Safety aspect – Check indicator
Do not use the bag if the oxygen indicator is pink.
Use the bag only if the oxygen indicator is yellow.[1-8]

2 MIX

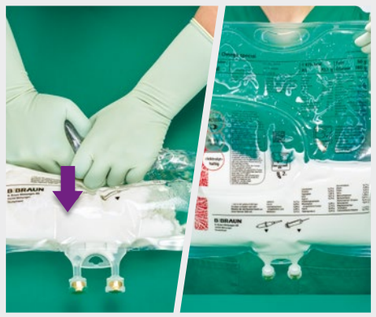
To open and mix the chambers sequentially, roll the bag with both hands, starting first by opening the peel seam that separates the top chamber (glucose) and the bottom chamber (amino acids).[1-8]

! Optional – Add Safety Aspect

Sterile medication port (white)
Remove the aluminium foil to add compatible additives via the medication port.[1-8]

Safety aspect
After adding the additives to the clear solution, a visual check is possible.

3 MIX



Continue applying pressure so that the peel seam, separating the middle chamber (lipids) and the bottom chamber, opens. Mix the contents of the bag thoroughly.

4 PREPARATION FOR INFUSION

Sterile infusion port (green)
Remove the aluminium foil and attach the infusion set to the infusion port. Use a non-vented infusion set or close the air vent when using a vented set. Hang the bag on an infusion stand and carry out infusion using the standard technique.

YOUR BENEFITS

- Increased safety through oxygen indicator
- Sterile port membranes
- Easy handling through stable ports
- Easy differentiation of ports thanks to color coding (white = additives, green = infusion)

Note: 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).

Product Specifications[1-8]

	Nutriflex® Omega peri			Nutriflex® Omega 38/120/40			Nutriflex® Omega 56/144/40			Nutriflex® Omega special w/o electrolytes		
Volume (ml)	**1,250**	**1,875**	**2,500**	**1,250**	**1,875**	**2,500**	**625**	**1,250**	**1,875**	**625**	**1,250**	**1,875**
Total energy (kcal)	955	1,435	1,910	1,265	1,900	2,530	740	1,475	2,215	740	1,475	2,215
Total energy (kJ)	4,000	6,000	8,000	5,300	7,950	10,600	3,090	6,175	9,260	3,090	6,175	9,265
Amino acids (g)	40	60	80	48	72	96	35.0	70.1	105.1	35.0	70.1	105.1
Nitrogen (g)	5.7	8.6	11.4	6.8	10.2	13.7	5	10	15	5	10	15
Glucose (g)	80	120	160	150	225	300	90	180	270	90	180	270
Medium chain triglycerides (g)	25.00	37.50	50.00	25.00	37.50	50.00	12.50	25.00	37.50	12.50	25.00	37.50
Soya-bean oil (g)	20.00	30.00	40.00	20.00	30.00	40.00	10.00	20.00	30.00	10.00	20.00	30.00
Omega-3 acid triglycerides (g)	5.000	7.500	10.00	5.000	7.500	10.00	2.500	5.000	7.500	2.500	5.000	7.500
Osmolarity (mOsm/l)	840	840	840	1,215	1,215	1,215	1,545	1,545	1,545	1,330	1,330	1,330
Electrolytes in mmol												
Sodium (Na^+)	50	75	100	50	75	100	33.5	67	100.5	–	–	–
Potassium (K^+)	30	45	60	35	52.5	70	23.5	47	70.5	–	–	–
Magnesium (Mg^{2+})	3.0	4.5	6.0	4.0	6.0	8.0	2.65	5.3	7.95	–	–	–
Calcium (Ca^{2+})	3.0	4.5	6.0	4.0	6.0	8.0	2.65	5.3	7.95	–	–	–
Phosphat	7.5	11.25	15.0	15.0	22.5	30	10	20	30	–	–	–
Chloride (Cl^-)	48	72	96	45	67.5	90	30	60	90	–	–	–
Acetate	40	60	80	45	67.5	90	30	60	90	–	–	–
Zinc (Zn^{2+})	0.03	0.045	0.06	0.03	0.045	0.06	0.02	0.04	0.06	–	–	–

Not all versions and bag sizes are available in all countries. Names can differ from country to country.

	Nutriflex® Lipid 32/64 peri			Nutriflex® Lipid 38/120 plus			Nutriflex® Lipid 56/144 special			Nutriflex® Lipid 56/144 special w/o electrolytes		
Volume (ml)	**1,250**	**1,875**	**2,500**	**1,250**	**1,875**	**2,500**	**625**	**1,250**	**1,875**	**625**	**1,250**	**1,875**
Total energy (kcal)	955	1,435	1,910	1,265	1,900	2,530	740	1,475	2,215	740	1,475	2,215
Total energy (kJ)	4,000	6,000	8,000	5,300	7,950	10,600	3,090	6,175	9,260	3,090	6,175	9,260
Amino acids (g)	40	60	80	48	72	96	35.0	70.1	105.1	35.0	70.1	105.1
Nitrogen (g)	5.7	8.6	11.4	6.8	10.2	13.7	5	10	15	5	10	15
Glucose (g)	80	120	160	150	225	300	90	180	270	90	180	270
Lipids (g)	50	75	100	50	75	100	25	50	75	25	50	75
Osmolarity (mOsm/l)	840	840	840	1,215	1,215	1,215	1,545	1,545	1,545	1,330	1,330	1,330
Electrolytes in mmol												
Sodium (Na^+)	50	75	100	50	75	100	33.5	67	100.5	–	–	–
Potassium (K^+)	30	45	60	35	52.5	70	23.5	47	70.5	–	–	–
Magnesium (Mg^{2+})	3.0	4.5	6.0	4.0	6.0	8.0	2.65	5.3	7.95	–	–	–
Calcium (Ca^{2+})	3.0	4.5	6.0	4.0	6.0	8.0	2.65	5.3	7.95	–	–	–
Phosphat	7.5	11.25	15.0	15.0	22.5	30	10	20	30	–	–	–
Chloride (Cl^-)	48	72	96	45	67.5	90	30	60	90	–	–	–
Acetate	40	60	80	45	67.5	90	30	60	90	–	–	–
Zinc (Zn^{2+})	0.03	0.045	0.06	0.03	0.045	0.06	0.02	0.04	0.06	–	–	–

Not all versions and bag sizes are available in all countries. Names can differ from country to country.

Product Information

Nutriflex® Omega 38/120/40 | Nutriflex® Omega 56/144/40 | Nutriflex® Omega peri

Emulsion for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

mixed and ready for use in 1,000 ml:	Nutriflex® Omega 38/120/40	Nutriflex® Omega 56/144/40	Nutriflex® Omega peri
from the upper left-hand chamber (glucose solution)			
Glucose monohydrate (g)	132.0	158.4	70.40
≙ anhydrous glucose (g)	120.0	144.0	64.00
Sodium dihydrogen phosphate dihydrate (g)	1.872	2.496	0.936
Zinc acetate dehydrate (mg)	5.264	7.024	5.280
from the upper right-hand chamber (fat emulsion)			
Medium-chain triglycerides (g)	20.00	20.00	20.00
Soya-bean oil refined (g)	16.00	16.00	16.00
Omega-3-acid triglycerides (g)	4.000	4.000	4.000
from the lower chamber (amino acid solution)			
Isoleucine (g)	2.256	3.284	1.872
Leucine (g)	3.008	4.384	2.504
Lysine hydrochloride (g)	2.728	3.980	2.272
≙ Lysine (g)	2.184	3.186	1.818
Methionine (g)	1.880	2.736	1.568
Phenylalanine (g)	3.368	4.916	2.808
Threonine (g)	1.744	2.540	1.456
Tryptophan (g)	0.544	0.800	0.456
Valine (g)	2.496	3.604	2.080
Arginine (g)	2.592	3.780	2.160
Histidine hydrochloride monohydrate (g)	1.624	2.368	1.352
≙ Histidine (g)	1.202	1.753	1.000
Alanine (g)	4.656	6.792	3.880
Aspartic acid (g)	1.440	2.100	1.200
Glutamic acid (g)	3.368	4.908	2.800
Glycine (g)	1.584	2.312	1.320
Proline (g)	3.264	4.760	2.720
Serine (g)	2.880	4.200	2.400
Sodium hydroxide (g)	0.781	1.171	0.640
Sodium chloride (g)	0.402	0.378	0.865
Sodium acetate trihydrate (g)	0.222	0.250	0.435
Potassium acetate (g)	2.747	3.689	2.354
Magnesium acetate tetrahydrate (g)	0.686	0.910	0.515
Calcium chloride dehydrate (g)	0.470	0.623	0.353
Amino acid content (g)	38	56.0	32
Nitrogen content (g)	5.4	8	4.6
Carbohydrate content (g)	120	144	64
Lipid content (g)	40	40	40
Electrolytes:			
Sodium (mmol)	40	53.6	40
Potassium (mmol)	28	37.6	24
Magnesium (mmol)	3.2	4.2	2.4
Calcium (mmol)	3.2	4.2	2.4
Zinc (mmol)	0.024	0.03	0.024
Chloride (mmol)	36	48	38
Acetate (mmol)	36	48	32
Phosphate (mmol)	12	16	6.0
Pharmaceutical Form:			
Energy in the form of lipid [kJ (kcal)]	1590 (380)	1590 (380)	1590 (380)
Energy in the form of carbohydrate [kJ (kcal)]	2010 (480)	2415 (575)	1075 (255)
Energy in the form of amino acids [kJ (kcal)]	635 (150)	940 (225)	535 (130)
Non-protein energy [kJ (kcal)]	3600 (860)	4005 (955)	2665 (635)
Total energy [kJ (kcal)]	4235 (1010)	4945 (1180)	3200 (765)
pH	5.0 - 6.0	5.0 - 6.0	5.0 - 6.0
Osmolality [mOsm/kg]	1540	2115	950
Theoretical osmolarity [mOsm/l]	1215	1545	840

LIST OF EXCIPIENTS
Citric acid monohydrate (for pH adjustment), egg lecithin, glycerol, sodium oleate, sodium hydroxide (for pH adjustment), all-rac-alpha-tocopherol, water for injections.

THERAPEUTIC INDICATIONS Nutriflex® Omega 38/120/40 | 56/144/40
Supply of energy, essential fatty acids including omega-3 and omega-6 fatty acids, amino acids, electrolytes and fluids for parenteral nutrition of patients in states of moderate to severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated. Nutriflex® Omega 38/120/40 | 56/144/40 is indicated in adults.

THERAPEUTIC INDICATIONS Nutriflex® Omega peri
Supply of energy, essential fatty acids including omega-3 and omega-6 fatty acids, amino acids, electrolytes and fluids for parenteral nutrition of patients in states of mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated. Nutriflex® Omega peri is indicated in adults.

POSOLOGY AND METHOD OF ADMINISTRATION
The dosage should be adapted to the patients' individual requirements. It is recommended that Nutriflex® Omega 38/120/40 | 56/144/40 | 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.

PAEDIATRIC POPULATION
Nutriflex® Omega 38/120/40 | 56/144/40 | peri is contraindicated in newborn infants, infants and toddlers < 2 years of age (see Contraindications). The safety and efficacy in children > 2 years have not been established yet. No data are available.

PATIENTS WITH RENAL/HEPATIC IMPAIRMENT
The doses should be adjusted individually in patients with hepatic or renal insufficiency (see Special warnings and precautions for use).

DURATION OF TREATMENT Nutriflex® Omega 38/120/40 | 56/144/40
The duration of treatment for the indications stated is not limited. During the administration of Nutriflex® Omega 38/120/40 | 56/144/40 it is necessary to provide an appropriate amount of trace elements and vitamins.

DURATION OF TREATMENT Nutriflex® Omega peri
The duration of treatment for the indications stated should not exceed 7 days via the same peripheral access. During the administration of Nutriflex® Omega peri it is necessary to provide an appropriate amount of trace elements and vitamins.

METHOD OF ADMINISTRATION Nutriflex® Omega 38/120/40 | 56/144/40
Intravenous use. For central venous infusion only.

METHOD OF ADMINISTRATION Nutriflex® Omega peri
Intravenous use. Infusion into a peripheral or central vein.

CONTRAINDICATIONS
- Hypersensitivity to the active substances, to egg, fish, peanut or soya protein or to any of the excipients
- Inborn errors of amino acid metabolism
- Severe hyperlipidaemia characterized by hypertriglyceridaemia (≥ 1000 mg/dl or 11.4 mmol/l)
- Severe coagulopathy
- Hyperglycaemia not responding to insulin doses of up to 6 units insulin/hour
- Acidosis
- Intrahepatic cholestasis
- Severe hepatic insufficiency
- Severe renal insufficiency in absence of renal replacement therapy
- Aggravating haemorrhagic diatheses
- Acute thrombo-embolic events, lipid embolism

On account of its composition Nutriflex® Omega must not be used in newborn infants, infants and toddlers under 2 years of age.

General contraindications to parenteral nutrition include:
- Unstable circulatory status with vital threat (states of collapse and shock)
- Acute phases of cardiac infarction and stroke
- Unstable metabolic condition (e.g. severe postaggression syndrome, coma of unknown origin)
- Disturbances of the electrolyte and fluid balance
- Acute pulmonary oedema
- Decompensated cardiac insufficiency

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 must 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 or symptom 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® Omega 38/120/40 | 56/144/40 | peri.

Depending on the patient's metabolic condition, occasional hypertriglyceridaemia may occur. If the plasma triglyceride concentration exceeds 4.6 mmol/l (400 mg/dl) during administration of lipids, it is recommended to reduce the infusion rate. The infusion must be interrupted if the plasma triglyceride concentration exceeds 11.4 mmol/l (1000 mg/dl), as these levels have been associated with acute pancreatitis.

Patients with impaired lipid metabolism Nutriflex® Omega 38/120/40 | 56/144/40
Nutriflex® Omega 38/120/40 | 56/144/40 should be administered cautiously to patients with disturbances of lipid metabolism with increased serum triglycerides, e.g. renal insufficiency, diabetes mellitus, pancreatitis, impaired hepatic function, hypothyroidism (with hypertriglyceridaemia), sepsis, and metabolic syndrome. If Nutriflex® Omega 38/120/40 | 56/144/40 is given to patients with these conditions, more frequent monitoring of serum triglycerides is necessary to assure triglyceride elimination and stable triglyceride levels below 11.4 mmol/l (1000 mg/dl). In combined hyperlipidaemias and in metabolic syndrome, triglyceride levels react to glucose, lipids and overnutrition. Adjust dose accordingly. Assess and monitor other lipid and glucose sources, and drugs interfering with their metabolism. The presence of hypertriglyceridaemia 12 hours after lipid administration also indicates a disturbance of lipid metabolism. Like all solutions containing carbohydrates, the administration of Nutriflex® Omega 38/120/40 | 56/144/40 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. An interruption of administration of the emulsion may be indicated if the blood glucose concentration rises to above 14 mmol/l (250 mg/dl) during administration. Refeeding or repletion of malnourished or depleted patients may cause hypokalaemia, hypophosphataemia and hypomagnesaemia. Close monitoring of serum electrolytes is mandatory. Adequate supplementation of electrolytes according to deviations from normal values is necessary. Controls of the serum electrolytes, the water balance, the acid-base balance, and of blood cell counts, coagulation status, hepatic and renal function are necessary. Substitution of electrolytes, vitamins and trace elements may be necessary as required. As Nutriflex® Omega 38/120/40 | 56/144/40 contains zinc, magnesium, calcium and phosphate, care should be taken when it is co-administered with solutions containing these substances. Nutriflex® Omega 38/120/40 | 56/144/40 is a preparation of complex composition. It is, therefore, strongly advisable not to add other solutions. Nutriflex® Omega 38/120/40 | 56/144/40 should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination. As with all intravenous solutions, especially for parenteral nutrition, strict aseptic precautions are necessary for the infusion of Nutriflex® Omega 38/120/40 | 56/144/40.

Patients with impaired lipid metabolism Nutriflex® Omega peri
Nutriflex® Omega peri should be administered cautiously to patients with disturbances of lipid metabolism with increased serum triglycerides, e.g. renal insufficiency, diabetes mellitus, pancreatitis, impaired hepatic function, hypothyroidism (with hypertriglyceridaemia), sepsis, and metabolic syndrome. If Nutriflex® Omega peri is given to patients with these conditions, more frequent monitoring of serum triglycerides is necessary to assure triglyceride elimination and stable triglyceride levels below 11.4 mmol/l (1000 mg/dl). In combined hyperlipidaemias and in metabolic syndrome, triglyceride levels react to glucose, lipids and overnutrition. Adjust dose accordingly. Assess and monitor other lipid and glucose sources, and drugs interfering with their metabolism. The presence of hypertriglyceridaemia 12 hours after lipid administration also indicates a disturbance of lipid metabolism. Like all solutions containing carbohydrates, the administration of Nutriflex® Omega 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. An interruption of administration of the emulsion may be indicated if the blood glucose concentration rises to above 14 mmol/l (250 mg/dl) during administration. Refeeding or repletion of malnourished or depleted patients may cause hypokalaemia, hypophosphataemia and hypomagnesaemia. Close monitoring of serum electrolytes is mandatory. Adequate supplementation of electrolytes according to deviations from normal values is necessary. Controls of the serum electrolytes, the water balance, the acid-base balance, and of blood cell counts, coagulation status, hepatic and renal function are necessary. Substitution of electrolytes, vitamins and trace elements may be necessary as required. As Nutriflex® Omega peri contains zinc, magnesium, calcium and phosphate, care should be taken when it is co-administered with solutions containing these substances. Nutriflex® Omega peri is a preparation of complex composition. It is, therefore, strongly advisable not to add other solutions. Additions can increase the overall osmolarity of the emulsion, consider with regard to peripheral administration and monitor the injection site. Nutriflex® Omega peri should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination. As with all intravenous solutions, especially for parenteral nutrition, strict aseptic precautions are necessary for the infusion of Nutriflex® Omega peri. Infusion in peripheral veins may cause thrombophlebitis. Monitor infusion site daily for signs of thrombophlebitis.

Paediatric population
There is as yet no clinical experience of the use of Nutriflex® Omega 38/120/40 | 56/144/40 | peri in children and adolescents.

Elderly patients
Basically the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age.

Patients with diabetes mellitus, impaired cardiac or renal function
Like all large-volume infusion solutions, Nutriflex® Omega 38/120/40 | 56/144/40 | peri should be administered with caution to patients with impaired cardiac or renal function. There is only limited experience of its use in patients with diabetes mellitus or renal failure.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy Nutriflex® Omega 38/120/40 | 56/144/40
There are no or limited amount of data from the use of Nutriflex® Omega 38/120/40 | 56/144/40 in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Parenteral nutrition may become necessary during pregnancy. Nutriflex® Omega 38/120/40 | 56/144/40 should only be given to pregnant women after careful consideration.

Pregnancy Nutriflex® Omega peri
There are no or limited amount of data from the use of Nutriflex® Omega peri in pregnant women. Animal studies undertaken with a lipid emulsion containing twice the amount of omega-3 acid triglycerides and a correspondingly smaller amount of omega-6 triglycerides as compared to Nutriflex® Omega peri do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Parenteral nutrition may become necessary during pregnancy. Nutriflex® Omega peri should only be given to pregnant women after careful consideration.

Breast-feeding
Components/metabolites of Nutriflex® Omega 38/120/40 | 56/144/40 | peri are excreted in human milk, but at therapeutic doses no effects on the breastfed newborns/infants are anticipated. Nevertheless, breast-feeding is not recommended for mothers on parenteral nutrition.

Fertility
No data from the use of Nutriflex® Omega 38/120/40 | 56/144/40 | peri available.

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® Omega 38/120/40 | 56/144/40 | peri.

Undesirable effects are listed according to their frequencies as follows:

Very common:	(≥ 1/10)
Common:	(≥ 1/100 to < 1/10)
Uncommon:	(≥ 1/1,000 to < 1/100)
Rare:	(≥ 1/10,000 to < 1/1,000)
Very rare:	(< 1/10,000)
Not known:	(Frequency cannot be estimated from the available data).

Blood and lymphatic system disorders
Rare: Hypercoagulation
Not Known: Leucopenia, thrombocytopenia

Immune system disorders
Rare: Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema)

Metabolism and nutrition disorders
Very rare: 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
Rare: Headache, drowsiness

Vascular disorders
Rare: Hypertension or hypotension, flush

Respiratory, thoracic and mediastinal disorders
Rare: Dyspnoea, cyanosis

Gastrointestinal disorders
Uncommon: Nausea, vomiting

Metabolism and nutrition disorders
Uncommon: Loss of appetite

Hepatobiliary disorders
Not known: Cholestasis

Skin and subcutaneous tissue disorders
Rare: Erythema, sweating

Musculoskeletal and connective tissue disorders
Rare: Pain in the back, bones, chest and lumbar region.

General disorders and administration site conditions
Rare: Elevated body temperature, feeling cold, chills
Very rare: Fat overload syndrome

Should adverse reactions occur or should the triglyceride level rise to above 3 mmol/l during infusion, the infusion should be stopped or, if necessary, continued at reduced dosage.

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, lack of appetite and hyperglycaemia are symptoms often related to conditions indicating parenteral nutrition or may be associated with parenteral nutrition.

Fat overload syndrome
Overdose of lipid emulsion or impaired capacity to eliminate triglycerides can lead to "fat overload syndrome". 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 diseases. This syndrome may also appear during severe hypertriglyceridaemia, even at the recommended infusion rate, or 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® Omega 38/120/40 | 56/144/40 | peri should be discontinued immediately.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

MARKETING AUTHORIZATION HOLDER
B.Braun Melsungen AG 34209 Melsungen, Germany

Last revision: 05/2017

Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Product Information

Nutriflex® Lipid 32/64 peri | Nutriflex® Lipid 38/120 plus | Nutriflex® Lipid 56/144 special | Nutriflex® Lipid 56/144 special without electrolytes

Emulsion for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

mixed and ready for use in 1,000 ml:	Nutriflex® Lipid 32/64 peri	Nutriflex® Lipid 38/120 plus	Nutriflex® Lipid 56/144 special	Nutriflex® Lipid 56/144 special without electrolytes
from the upper left-hand chamber (glucose solution)				
Glucose monohydrate (g)	70.40	132.0	158.4	158.4
≙ anhydrous glucose (g)	64.00	120.0	144.0	144.0
Sodium dihydrogen phosphate dihydrate (g)	0.936	1.872	2.496	-
Zinc acetate dehydrate (mg)	5.280	5.264	7.024	-
from the middle chamber (fat emulsion)				
Soya-bean oil refined (g)	20.00	20.00	20.00	20.00
Medium-chain triglycerides (g)	20.00	20.00	20.00	20.00
from the bottom chamber (amino acid solution)				
Isoleucine (g)	1.872	2.256	3.284	3.284
Leucine (g)	2.504	3.008	4.384	4.384
Lysine hydrochloride (g)	2.272	2.728	3.980	3.576
≙ Lysine (g)	1.818	2.184	3.186	3.184
Methionine (g)	1.568	1.880	2.736	2.736
Phenylalanine (g)	2.808	3.368	4.916	4.916
Threonine (g)	1.456	1.744	2.540	2.540
Tryptophan (g)	0.456	0.544	0.800	0.800
Valine (g)	2.080	2.496	3.604	3.604
Arginine (g)	2.160	2.592	3.780	-
Histidine hydrochloride monohydrate (g)	1.352	1.624	2.368	-
≙ Histidine (g)	1.000	1.202	1.753	1.752
Alanine (g)	3.880	4.656	6.792	6.792
Aspartic acid (g)	1.200	1.440	2.100	2.100
Glutamic acid (g)	2.800	3.368	4.908	4.908
Glycine (g)	1.320	1.584	2.312	2.312
Proline (g)	2.720	3.264	4.760	4.760
Serine (g)	2.400	2.880	4.200	4.200
Sodium hydroxide (g)	0.640	0.781	1.171	-
Sodium chloride (g)	0.865	0.402	0.378	-
Sodium acetate trihydrate (g)	0.435	0.222	0.250	-
Potassium acetate (g)	2.345	2.747	3.689	-
Magnesium acetate tetrahydrate (g)	0.515	0.686	0.910	-
Calcium chloride dehydrate (g)	0.353	0.470	0.623	-
Amino acid content (g)	32	38	56.0	56.0
Nitrogen content (g)	4.6	5.4	8	8
Carbohydrate content (g)	64	120	144	144
Lipid content (g)	40	40	40	40
Electrolytes:				
Sodium (mmol)	40	40	53.6	-
Potassium (mmol)	24	28	37.6	-
Magnesium (mmol)	2.4	3.2	4.2	-
Calcium (mmol)	2.4	3.2	4.2	-
Zinc (mmol)	0.024	0.024	0.03	-
Chloride (mmol)	38	36	48	-
Acetate (mmol)	32	36	48	-
Phosphate (mmol)	6.0	12	16	-
Pharmaceutical Form:				
Energy in the form of lipid [kJ (kcal)]	1590 (380)	1590 (380)	1590 (380)	1590 (380
Energy in the form of carbohydrate [kJ (kcal)]	1075 (255)	2010 (480)	2415 (575)	2415 (575)
Energy in the form of amino acids [kJ (kcal)]	535 (130)	635 (150)	940 (225)	940 (225)
Non-protein energy [kJ (kcal)]	2665 (635)	3600 (860)	4005 (955)	4005 (955)
Total energy [kJ (kcal)]	3200 (765)	4235 (1010)	4945 (1180)	4945 (1180)
pH	5.0 - 6.0	5.0 - 6.0	5.0 - 6.0	5.0 - 6.0
Osmolality [mOsm/kg]	950	1540	2115	1840
Theoretical osmolarity [mOsm/l]	840	1215	1545	1330

LIST OF EXCIPIENTS
Citric acid monohydrate (for pH adjustment), egg lecithin, glycerol, sodium oleate, all-rac-alpha-tocopherol, water for injections.

THERAPEUTIC INDICATIONS
Supply of energy, essential fatty acids, amino acids, electrolytes and fluids for parenteral nutrition of patients in states of mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated. Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes is indicated in adults, adolescents and children older than two years.

POSOLOGY AND METHOD OF ADMINISTRATION
The dosage should be adapted to the patients' individual requirements. It is recommended that Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes be administered continuously. A stepwise increase of the infusion rate over the first 30 minutes up to the desired infusion rate avoids possible complications.

PAEDIATRIC POPULATION
Newborn infants, infants and toddlers less than two years of age
Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes is contraindicated in newborn infants, infants and toddlers < 2 years of age (see Contraindications).
Children from 2 to 13 years of age
The given dosage recommendations are guiding data based on average requirements. The dosage should be individually adapted according to age, developmental 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.

PATIENTS WITH RENAL /HEPATIC IMPAIRMENT
The doses should be adjusted individually in patients with hepatic or renal insufficiency (see Sepcial warnings and precautions for use).

DURATION OF TREATMENT Nutriflex® Lipid 32/64 peri
The duration of treatment for the indications stated should not exceed 7 days. During the administration of Nutriflex® Lipid 32/64 peri it is necessary to provide an appropriate amount of trace elements and vitamins.

DURATION OF TREATMENT Nutriflex® Lipid 38/120 plus | 56/144 special | 56/144 special without electrolytes
The duration of treatment for the indications stated is not limited. During the administration of Nutriflex® Lipid 38/120 plus | 56/144 special | 56/144 special without electrolytes it is necessary to provide an appropriate amount of electrolytes, trace elements and vitamins.

METHOD OF ADMINISTRATION Nutriflex® Lipid 32/64 peri
Intravenous use. Infusion into a peripheral or central vein.

METHOD OF ADMINISTRATION Nutriflex® Lipid 38/120 plus | 56/144 special | 56/144 special without electrolytes
Intravenous use. For central venous infusion only.

CONTRAINDICATIONS
- Hypersensitivity to the active substances, to egg, fish, peanut or soya protein or to any of the excipients
- Inborn errors of amino acid metabolism
- Severe hypertriglyceridaemia (≥ 1000 mg/dl or 11.4 mmol/l)
- Severe coagulopathy
- Hyperglycaemia not responding to insulin doses of up to 6 units insulin/hour
- Acidosis
- Intrahepatic cholestasis
- Severe hepatic insufficiency
- Severe renal insufficiency in absence of renal replacement therapy
- Aggravating haemorrhagic diatheses
- Acute thrombo-embolic events, lipid embolism

On account of its composition Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes must not be used in newborn infants, infants and toddlers under 2 years of age.

General contraindications to parenteral nutrition include:
- Unstable circulatory status with vital threat (states of collapse and shock)
- Acute phases of cardiac infarction and stroke
- Unstable metabolic condition (e. g. severe postaggression syndrome, coma of unknown origin)
- Inadequate cellular oxygen supply
- Disturbances of the electrolyte and fluid balance
- Acute pulmonary oedema
- Decompensated cardiac insufficiency

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 must 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 or symptom 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 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes.

Depending on the patient's metabolic condition, occasional hypertriglyceridaemia may occur. If the plasma triglyceride concentration exceeds 4.6 mmol/l (400 mg/dl) during administration of lipids, it is recommended to reduce the infusion rate. The infusion must be interrupted if the plasma triglyceride concentration exceeds 11.4 mmol/l (1000 mg/dl), as these levels have been associated with acute pancreatitis.

Patients with impaired lipid metabolism
Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes should be administered cautiously to patients with disturbances of lipid metabolism with increased serum triglycerides, e. g. renal insufficiency, diabetes mellitus, pancreatitis, impaired hepatic function, hypothyroidism (with hypertriglyceridaemia), sepsis, and metabolic syndrome. If Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes is given to patients with these conditions, more frequent monitoring of serum triglycerides is necessary to assure triglyceride elimination and stable triglyceride levels below 11.4 mmol/l (1000 mg/dl). In combined hyperlipidaemias and in metabolic syndrome, triglyceride levels react to glucose, lipids and overnutrition. Adjust dose accordingly. Assess and monitor other lipid and glucose sources, and drugs interfering with their metabolism. The presence of hypertriglyceridaemia 12 hours after lipid administration also indicates a disturbance of lipid metabolism. Like all solutions containing carbohydrates, the administration of Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes 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. An interruption of administration of the emulsion may be indicated if the blood glucose concentration rises to above 14 mmol/l (250 mg/dl) during administration. 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, the acid-base balance, and of blood cell counts, coagulation status, hepatic and renal function are necessary. Substitution of electrolytes, vitamins and trace elements may be necessary as required. As Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes contains zinc, magnesium, calcium and phosphate, care should be taken when it is co-administered with solutions containing these substances. Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytesi is a preparation of complex composition. It is, therefore, strongly advisable not to add other solutions. Additions can increase the overall osmolarity of the emulsion, consider with regard to peripheral administration and monitor the injection site. Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination. As with all intravenous solutions, especially for parenteral nutrition, strict aseptic precautions are necessary for the infusion of Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes. Infusion in peripheral veins may cause thrombophlebitis. Monitor infusion site daily for signs of thrombophlebitis.

Elderly patients
Basically the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age.

Patients with diabetes mellitus, impaired cardiac or renal function
Like all large-volume infusion solutions, Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes should be administered with caution to patients with impaired cardiac or renal function. There is only limited experience of its use in patients with diabetes mellitus or renal failure.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy
There are no or limited amount of data from the use of Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Parenteral nutrition may become necessary during pregnancy. Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes should only be given to pregnant women after careful consideration.

Breast-feeding
Components/metabolites of Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes are excreted in human milk, but at therapeutic doses no effects on the breastfed newborns/infants are anticipated. Nevertheless, breast-feeding is not recommended for mothers on parenteral nutrition.

Fertility
No data from the use of Nutriflex® Lipid 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes available.

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 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes.

Undesirable effects are listed according to their frequencies as follows:

Very common:	(≥ 1/10)
Common:	(≥ 1/100 to < 1/10)
Uncommon:	(≥ 1/1,000 to < 1/100)
Rare:	(≥ 1/10,000 to < 1/1,000)
Very rare:	(< 1/10,000)
Not known:	(Frequency cannot be estimated from the available data).

Blood and lymphatic system disorders
Rare: Hypercoagulation
Not Known: Leucopenia, thrombocytopenia

Immune system disorders
Rare: Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema)

Metabolism and nutrition disorders
Very rare: 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
Rare: Headache, drowsiness

Vascular disorders
Rare: Hypertension or hypotension, flush

Respiratory, thoracic and mediastinal disorders
Rare: Dyspnoea, cyanosis

Gastrointestinal disorders
Uncommon: Nausea, vomiting

Metabolism and nutrition disorders
Uncommon: Loss of appetite

Hepatobiliary disorders
Not known: Cholestasis

Skin and subcutaneous tissue disorders
Rare: Erythema, sweating

Musculoskeletal and connective tissue disorders
Rare: Pain in the back, bones, chest and lumbar region.

General disorders and administration site conditions
Common: After a few days, vein irritation, phlebitis or thrombophlebitis may occur.
Rare: Elevated body temperature, feeling cold, chills
Very rare: Fat overload syndrome

If signs of vein wall irritation, phlebitis or thrombophlebitis occur, change of the infusion site should be considered. Should adverse reactions occur, the infusion must be stopped. 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 Special warnings and precautions for use). 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 32/64 peri | 38/120 plus | 56/144 special | 56/144 special without electrolytes should be discontinued immediately.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

NOTE
Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

MARKETING AUTHORIZATION HOLDER
B.Braun Melsungen AG 34209 Melsungen, Germany

Last revision: 05/2017

Prescription only

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Product Information

Lipoplus®/Lipidem®

COMPOSITION
1,000 ml of emulsion contains

Medium-chain triglycerides	100.0 g
Soya-bean oil, refined	80.0 g
Omega-3-acid triglycerides	20.0 g
Essential fatty acid content per liter:	
Linoleic acid (omega-6)	48.0 – 58.0 g
Alpha-linolenic acid (omega-3)	5.0 – 11.0 g
Eicosapentaenoic acid and Docosahexaenoic acid (omega-3)	8.6 – 17.2 g
Caloric content per liter:	7,900 kJ ≈ 1,910 kcal
Osmolality:	approx. 410 mOsm/kg
Titration acidity or alkalinity (to pH 7.4):	less than 0.5 mmol/l NaOH or HCl
pH:	6.5 - 8.5

INDICATIONS
Supply of energy, including a readily utilisable lipid component (medium-chain triglycerides) and essential omega-6 fatty acids and omega-3 fatty acids, as part of parenteral nutrition when oral or enteral nutrition is impossible, insufficient or contraindicated. Lipoplus® is indicated in adults, preterm and term neonates, infants and toddlers, children and adolescents.

CONTRAINDICATIONS
Hypersensitivity to the active substances, to egg, fish, peanut or soya protein or to any of the excipients
- Severe hypertriglyceridaemia (≥ 1000 mg/dl or 11.4 mmol/l)
- Severe coagulopathy
- Intrahepatic cholestasis
- Severe hepatic insufficiency
- Severe renal insufficiency in absence of renal replacement therapy
- Acute thromboembolic events, fat embolism
- Acidosis

General contraindications to parenteral nutrition include:
- Unstable circulatory status with vital threat (states of collapse and shock)
- Acute phases of cardiac infarction or stroke
- Unstable metabolic conditions (e. g. decompensated diabetes mellitus, severe sepsis, coma of unknown origin)
- Inadequate cellular oxygen supply
- Disturbances of the electrolyte and fluid balance
- Acute pulmonary oedema
- Decompensated cardiac insufficiency

FERTILITY, PREGNANCY AND LACTATION
Pregnancy
There are no or limited amount of data from the use of Lipoplus® in pregnant women. Animal studies undertaken with a lipid emulsion containing twice the amount of omega-3 acid triglycerides and a correspondingly smaller amount of omega-6-acid triglycerides as compared to Lipoplus® do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Parenteral nutrition may become necessary during pregnancy. Lipoplus® should only be administered to pregnant women after careful benefit-risk consideration.

Breastfeeding
Components/metabolites of Lipoplus® are excreted in human milk, but at therapeutic doses of Lipoplus® no effects on the breastfed newborns/infants are anticipated. In general, breastfeeding is not recommended to mothers on parenteral nutrition.
Fertility
No data from the use of Lipoplus® available.

UNDESIRABLE EFFECTS
The following listing includes a number of systemic adverse reactions that may be associated with the use of Lipoplus®. Under the conditions of correct use, in terms of dosing, monitoring, observation of safety restrictions and instructions, most of them are very rare (< 1/10,000).

Undesirable effects are listed according to their frequencies as follows:

Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from the available data)

Blood and lymphatic system disorders
Very rare: Hypercoagulation; Not known: Leucopenia, thrombocytopenia

Immune system disorders
Very rare: Allergic reactions (e. g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema)

Metabolism and nutrition disorders
Very rare: Hyperlipidaemia, metabolic acidosis

The frequency of these adverse reactions is dose-dependent and may be higher under conditions of absolute or relative overdose.
Very rare: Hyperglycaemia

Nervous system disorders
Very rare: Headache, drowsiness

Vascular disorders
Very rare: Hypertension or hypotension, flush

Respiratory, thoracic and mediastinal disorders
Very rare: Dyspnoea, cyanosis

Gastrointestinal disorders
Very rare: Nausea, vomiting, loss of appetite 012

Skin and subcutaneous tissue disorders
Very rare: Erythema, sweating

Hepatobiliary disorders
Not known: Cholestasis

Musculoskeletal and connective tissue disorders
Rare: Pain in the back, bones, chest and lumbar region

General disorders and administration site conditions
Very rare: Elevated body temperature, feeling cold, chills, fat overload syndrome (see below).

Should adverse reactions occur, the infusion must be stopped.
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. 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 diseases. 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 Lipoplus® must be discontinued immediately.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 03/2016

Prescription only

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Product Information & Literature

Lipofundin® MCT/LCT*

COMPOSITION

1000 ml emulsion contain	Lipofundin® MCT/LCT 10%	Lipofundin® MCT/LCT 20%
Soybean oil	50.0 g	100.0 g
Mediumchain Triglycerides	50.0 g	100.0 g
Glycerol	25.0 g	25.0 g
Egg yolk phospholipids*	8.0 g	12.0 g
Sodium Oleate, α-Tocopherol*, Water for injections		
Caloric Value (kcal):	1022	1908
Theor. osmolarity (mOsmo/L):	345	380
pH:	6.5-8.8	6.5-8.5

* The amount of egg yolk phospholipids and α-tocopherol can vary is some countries. Please refer to the country representative. Soybean oil is a refined natural product containing neutral triglycerides of predominantly unsaturated fatty acids. Medium-chain triglycerides are a mixture of neutral triglycerides of mainly caprylic (about 60%) and capric acid (about 40%).

INDICATIONS
Lipofundin® MCT/LCT is indicated as a source of calories and essential fatty acids for patients requiring Parenteral Nutrition.

CONTRAINDICATIONS
The administration of Lipofundin® MCT/LCT is contraindicated in patients demonstrating disturbances in normal fat metabolism such as pathologic hyperlipaemia, lipoid nephrosis, or acute pancreatitis if accompanied by hyperlipaemia. It is further contraindicated in patients with ketoacidosis or hypoxia, in thromboembolism and in acute shock states.

PRECAUTIONS FOR USE
Caution should be exercised in administering intravenous fat emulsions in patients with metabolic acidosis, severe liver damage, pulmonary disease, sepsis, diseases of the reticuloendothelial system, anaemia or blood coagulation disorders or when there is danger of fat embolism. Administration of Lipofundin® MCT/LCT should be accompanied by simultaneous carbohydrate infusions making up to 40% (at least) of the total calorie intake. When Lipofundin® MCT/LCT is administered, the patient's capacity to eliminate the infused fat from the circulation must be monitored. The lipaemia must clear between daily infusions. Especially where fat emulsions are administered for extended periods of time, the patient's haemogram, blood coagulation, liver function and platelet count should be closely monitored.Paediatric patients: studies have shown the safety and effectiveness of Lipofundin® MCT/LCT as part of total Parenteral Nutrition in neonates and older children.

Lipofundin® MCT/LCT has been aproved for usage in this patient population in some countries. Registration procedures are currently pursued in other countries. As long as approval has not been obtained in a specific country it is up to the judgement of the responsible physician whether or not to use Lipofundin® MCT/LCT in this patient group.

Use in pregnancy and lactation
The safety of Lipofundin® MCT/LCT during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard. Nevertheless, medicines should not be used in pregnancy, especially during the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

SPECIAL WARNINGS
The too rapid infusion of fat emulsions can cause fluid and/or fat overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, pulmonary oedema, impaired pulmonary diffusion capacity. A too rapid infusion of Lipofundin® MCT/LCT can also cause hyperketonaemia and/or metabolic acidosis, especially when carbohydrates are not administered simultaneously.

MARKETING AUTHORIZATION HOLDER
B.Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 10/2016

Prescription only.

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

LITERATURE

1. SmPC Nutriflex® Lipid 32/64 peri, Status of latest information: April 2017
2. SmPC Nutriflex® Lipid 38/120 plus, Status of latest information: April 2017
3. SmPC Nutriflex® Lipid 56/144 special, Status of latest information: April 2017
4. SmPC Nutriflex® Lipid 56/144 special without electrolytes, Status of latest information: April 2017
5. SmPC Nutriflex® Omega peri, Status of latest information: April 2017
6. SmPC Nutriflex® Omega 38/120/40, Status of latest information: April 2017
7. SmPC Nutriflex® Omega 56/144/40, Status of latest information: April 2017
8. SmPC Nutriflex® Omega special without electrolytes, Status of latest information: April 2017

Notes

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Date of last revision: 06.2018