B BRAUN
SHARING EXPERTISE

COLOR
YOUR
THERAPIES

Nutriflex® 3-Chamber Bags for Parenteral Nutrition

Upgrade Nutrition Therapy

CHECK-UP.

Compatibility and stability data are extremely important for me as a pharmacist. EasyComp and Compactus are my go to tools when I want to check on the stability and compatibility of additives. These tools are supported by an extensive data base of compatibility studies for Nutriflex® 3-Chamber bags and single nutrient solutions. Convenience of information at my fingertips.

Nutriflex® 3-Chamber bags offer easy handling, reducing the time needed from preparation to patient infusion. The flexible bag material makes opening and mixing of the bags a breeze, while the stable and rigid ports reduces the risk of needle stick injury. That is why Nutriflex® makes me smile as patient care should be simple.

SPEED-UP.

FEED-UP.

Nutrition Support and Nutrition Therapy! These topics have always been of great importance to me. Either way, fighting malnutrition is an efficient way that leads to better patient outcome. Nutriflex® 3-Chamber bags have a wide range of offerings suitable for a diverse group of patients, making the most of your therapeutic options. Feeding is caring!

The Bag Design

Clear – Practical – User friendly

PRACTICAL INFORMATION
- List of macronutrient and caloric content

CLEAR LABELING
- Of the volume in ml

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

QUICK REFERENCE FOR KEY INFORMATION
- Type of lipid emulsion in the bag (Lipofundin® or Lipidem® / Lipoplus®)
- Administration route (peripheral or / and central venous)
- With or without electrolytes

Infusion port

Additive port

ADVANCED PORT SYSTEM WITH STABEL, STERILE PORTS

May reduce needle stick injuries
- Due to a bigger diameter and longer port necks
- Easy-to-grip

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

Sterile, stable and self-sealing ports

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]

UNDERSTANDING YOUR NEEDS.

The bag design of Nutriflex® 3-Chamber Bags is dedicated to enhancing convenience and safety with information at a glance:

- 100 % PVC, DEHP and latex free
- Clear and user friendly labeling at a glance
- Innovative oxygen indicator provides quality assurance
- Tamper evident ports with a sterile surface enhance the sense of security
- Self-sealing and stable ports facilitate handling
- Color coding simplifies differentiation of bag versions and ports
- Since 1998 our commitment for your convenience

Extended Product Range

All features at glance

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.

Product	Color code	Bag sizes	Peripheral Venous	Central Venous	Electrolytes
Nutriflex® Omega peri*[5] 38 g/l amino acids 120 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.

Nutriflex® Lipid*

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

Licensed for use in children older than 2 years old, adolescents and adults.

MEDIUM-CHAIN TRIGLYCERIDES
Source of readily available energy

SOYA BEAN OIL
Covers essential fatty acid requirements

Nutriflex® Omega*

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

For the use in adults.

MEDIUM-CHAIN TRIGLYCERIDES
Source of readily available energy

SOYA BEAN OIL
Covers essential fatty acid requirements

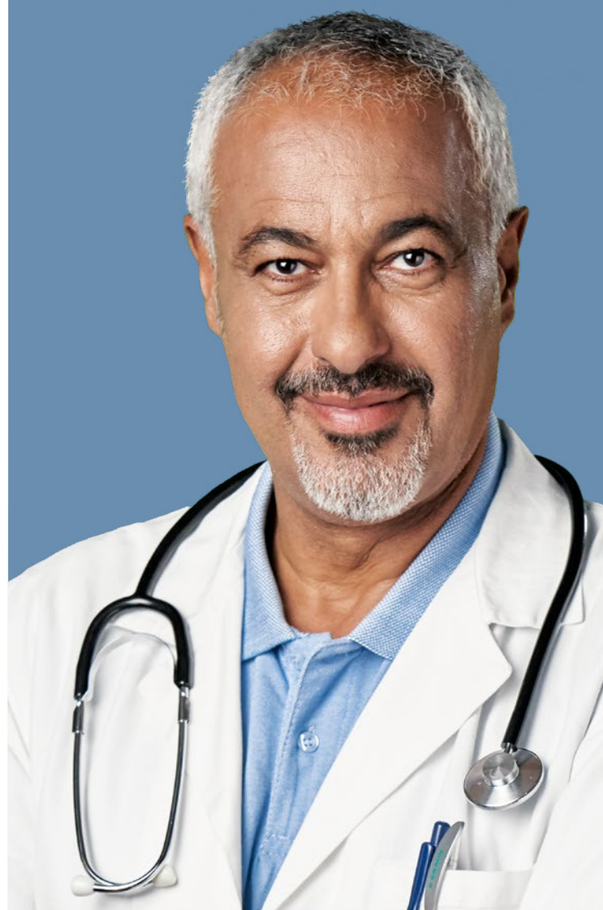
OMEGA-3-ACID TRIGLYCERIDES
From fish oil for the delivery of EPA and DHA

NEED-BASED NUTRITION.

As the innovator of the proven MCT/LCT technology, improving patient outcomes is always our focus. Our products are tailored and adapted to individual patients' needs.

Lipofundin® MCT/LCT
- may be liver-protective[9]
- may improve the lung function[10]
- may reduce morbidity and mortality[11]

Lipidem®/Lipoplus®
- may reduce the risks of nosocomial infections[12]
- may improve the O_2 gas exchange[13]
- may reduce the hospital length of stay[14]



Medication Safety

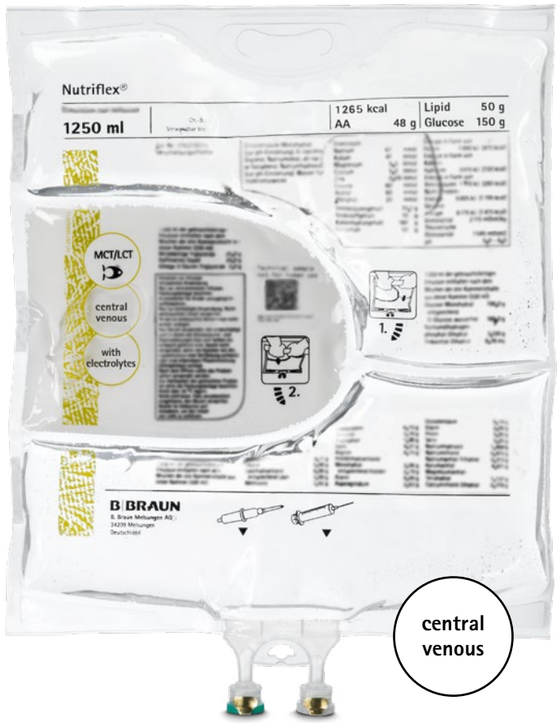
Easy differentiation by color codes

INCREASE PATIENT SAFETY

We encourage constructive dialog with our customers, in order to identify effective solutions that increase safety in the clinical environment.

The color codings of the Nutriflex® 3-Chamber bags have always been a feature since the first launch in 1998.

NUTRIFLEX® OMEGA PLUS
NUTRIFLEX® LIPID PLUS



NUTRIFLEX® OMEGA SPECIAL
NUTRIFLEX® LIPID SPECIAL

WITH AND WITHOUT ELECTROLYTES

NUTRIFLEX® OMEGA PERI
NUTRIFLEX® LIPID PERI

DESIGNED TO MAKE YOU SMILE.

Nutriflex® 3-Chamber Bags have been developed to bring increased ease and safety into the life of nurses and of everyone who prepares parenteral nutrition.

- The labeling on the carton provides first-sight-orientation
- Key information is easily identifiable
- User instructions are clearly outlined in diagrams on the bag
- Sequential mixing is possible in accordance with the ASPEN mixing protocols

Mix – Ready – Infuse

Soft material, easy to handle

EASY HANDLING.

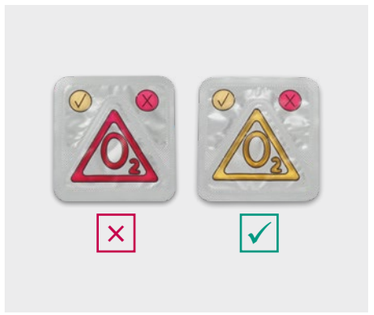
1 PREPARATION

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]

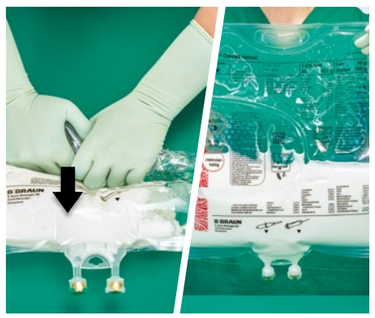
! Optional – Add

STERILE MEDICATION PORT (WHITE)
Remove the aluminium foil to add compatible additives via the medication port.[1-8]

Safety Aspect

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.

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).

Additives from B. Braun

Viant®
All-in-one product that fulfills the daily need for lipid and water soluble vitamins of PN patients.

Tracutil®
Trace elements for use in parenteral nutrition covering basic requirements.

Our Product Specifications[1-8]

AT A GLANCE.

	Nutriflex® Omega peri			Nutriflex® Omega plus			Nutriflex® Omega special			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	–	–	–

Antioxidant: Additional Vitamin E approx. 200 mg all-rac-alpha-tocopherol / L inside

	Nutriflex® Lipid peri			Nutriflex® Lipid plus			Nutriflex® Lipid special			Nutriflex® Lipid 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	–	–	–

Antioxidant: Additional Vitamin E approx. 200 mg all-rac-alpha-tocopherol / L inside

Additions to Nutriflex® Lipid may increase its osmolarity. Vitamins and trace elements should be added just prior to use! There may be some degradation during shelf life. See manufacturer's recommendation. [a] Nutriflex® Lipid special also exist as electrolyte-free version (special: 1330 mOsm / l). *Not all versions and bag volumes will be marketed in each country.

COLOR
YOUR
THERAPIES

Nutriflex®

3-Chamber Bags

For more than 20 years, B. Braun has offered the first ready to use standardized 3-chamber bags in support of patients who rely on parenteral nutrition. This has given health care professionals an efficient way of feeding their patients while fulfilling their nutritional requirements. Since the initial launch, the 3-chamber bag has established itself as a valuable pillar in nutrition therapy.

To this day, we are passionately developing smart solutions that make therapies safer and more effective trough constructive dialogue with our customers. For example, the concept of color coding and the pionneering development of lipid emulsion technology has improved the efficiancy and safety for providing nutrition.

Patients in more than 50 countries around the world trust in our Nutriflex® 3-chamber bags – engineered and manufactured in Germany.

We at B. Braun are dedicated to improving qualtiy of care.

>20

YEARS OF EXPERIENCE

COLOR CODED

INVENTORS OF MCT/LCT TECHNOLOGY

DESIGNED TO ENHANCE SAFETY

>50

COUNTRIES TRUST IN NUTRIFLEX®

MANUFACTURED IN GERMANY

Product Information

Nutriflex® Omega peri | Nutriflex® Omega 38/120/40 | Nutriflex® Omega 56/144/40 | Nutriflex® Omega special w/o electrolytes

Emulsion for infusion

COMPOSITION

The ready-for-use emulsion for intravenous infusion contains after mixing the chamber contents:	Nutriflex® Omega peri				Nutriflex® Omega 38/120/40				Nutriflex® Omega 56/144/40				Nutriflex® Omega special w/o electrolytes			
from the top chamber (glucose solution)	1000 ml	1250 ml	1875 ml	2500 ml	1000 ml	1250 ml	1875 ml	2500 ml	1000 ml	625 ml	1250 ml	1875 ml	1000 ml	625 ml	1250 ml	1875 ml
Glucose monohydrate (g)	70.40	88.00	132.0	176.0	132.0	165.0	247.5	330.0	158.4	99.00	198.0	297.0	158.4	99.00	198.0	297.0
equivalent to glucose (g)	64.00	80.00	120.0	160.0	120.0	150.0	225.0	300.0	144.0	90.00	180.0	270.0	144.0	90.00	180.0	270.0
Sodium dihydrogen phosphate dihydrate (g)	0.936	1.170	1.755	2.340	1.872	2.340	3.510	4.680	2.496	1.560	3.120	4.680	-	-	-	-
Zinc acetate dehydrate (mg)	5.280	6.600	9.900	13.20	5.264	6.580	9.870	13.16	7.024	4.390	8.780	13.17	-	-	-	-
from the middle chamber (fat emulsion)																
Medium-chain triglycerides (g)	20.00	25.00	37.50	50.00	20.00	25.00	37.50	50.00	20.00	12.50	25.00	37.50	20.00	12.50	25.00	37.50
Soya-bean oil refined (g)	16.00	20.00	30.00	40.00	16.00	20.00	30.00	40.00	16.00	10.00	20.00	30.00	16.00	10.00	20.00	30.00
Omega-3-acid triglycerides (g)	4.000	5.000	7.500	10.00	4.000	5.000	7.500	10.00	4.000	2.500	5.000	7.500	4.000	2.500	5.000	7.500
from the bottom chamber (amino acid solution)																
Isoleucine (g)	1.872	2.340	3.510	4.680	2.256	2.820	4.230	5.640	3.284	2.053	4.105	6.158	3.284	2.053	4.105	6.158
Leucine (g)	2.504	3.130	4.695	6.260	3.008	3.760	5.640	7.520	4.384	2.740	5.480	8.220	4.384	2.740	5.480	8.220
Lysine hydrochloride (g)	2.272	2.840	4.260	5.680	2.728	3.410	5.115	6.820	3.980	2.488	4.975	7.463	3.576	2.235	4.470	6.705
equivalent to lysine (g)	1.818	2.273	3.410	4.546	2.184	2.729	4.094	5.459	3.186	1.991	3.982	5.973	3.184	1.990	3.979	5.969
Methionine (g)	1.568	1.960	2.940	3.920	1.880	2.350	3.525	4.700	2.736	1.710	3.420	5.130	2.736	1.710	3.420	5.130
Phenylalanine (g)	2.808	3.510	5.265	7.020	3.368	4.210	6.315	8.420	4.916	3.073	6.145	9.218	4.916	3.073	6.145	9.218
Threonine (g)	1.456	1.820	2.730	3.640	1.744	2.180	3.270	4.360	2.540	1.588	3.175	4.763	2.540	1.588	3.175	4.763
Tryptophan (g)	0.456	0.570	0.855	1.140	0.544	0.680	1.020	1.360	0.800	0.500	1.000	1.500	0.800	0.500	1.000	1.500
Valine (g)	2.080	2.600	3.900	5.200	2.496	3.120	4.680	6.240	3.604	2.253	4.505	6.758	3.604	2.253	4.505	6.758
Arginine (g)	2.160	2.700	4.050	5.400	2.592	3.240	4.860	6.480	3.780	2.363	4.725	7.088	3.780	2.363	4.725	7.088
Histidine hydrochloride monohydrate (g)	1.352	1.690	2.535	3.380	1.624	2.030	3.045	4.060	2.368	1.480	2.960	4.440	-	-	-	-
equivalent to histidine (g)	1.000	1.251	1.876	2.502	1.202	1.503	2.254	3.005	1.753	1.095	2.191	3.286	1.752	1.095	2.190	3.285
Alanine (g)	3.880	4.850	7.275	9.700	4.656	5.820	8.730	11.64	6.792	4.245	8.490	12.73	6.792	4.245	8.490	12.73
Aspartic acid (g)	1.200	1.500	2.250	3.000	1.440	1.800	2.700	3.600	2.100	1.313	2.625	3.938	2.100	1.313	2.625	3.938
Glutamic acid (g)	2.800	3.500	5.250	7.000	3.368	4.210	6.315	8.420	4.908	3.068	6.135	9.203	4.908	3.068	6.135	9.203
Glycine (g)	1.320	1.650	2.475	3.300	1.584	1.980	2.970	3.960	2.312	1.445	2.890	4.335	2.312	1.445	2.890	4.335
Proline (g)	2.720	3.400	5.100	6.800	3.264	4.080	6.120	8.160	4.760	2.975	5.950	8.925	4.760	2.975	5.950	8.925
Serine (g)	2.400	3.000	4.500	6.000	2.880	3.600	5.400	7.200	4.200	2.625	5.250	7.875	4.200	2.625	5.250	7.875
Sodium hydroxide (g)	0.640	0.800	1.200	1.600	0.781	0.976	1.464	1.952	1.171	0.732	1.464	2.196	-	-	-	-
Sodium chloride (g)	0.865	1.081	1.622	2.162	0.402	0.503	0.755	1.006	0.378	0.237	0.473	0.710	-	-	-	-
Sodium acetate trihydrate (g)	0.435	0.544	0.816	1.088	0.222	0.277	0.416	0.554	0.250	0.157	0.313	0.470	-	-	-	-
Potassium acetate (g)	2.354	2.943	4.415	5.886	2.747	3.434	5.151	6.868	3.689	2.306	4.611	6.917	-	-	-	-
Magnesium acetate tetrahydrate (g)	0.515	0.644	0.966	1.288	0.686	0.858	1.287	1.716	0.910	0.569	1.137	1.706	-	-	-	-
Calcium chloride dehydrate (g)	0.353	0.441	0.662	0.882	0.470	0.588	0.882	1.176	0.623	0.390	0.779	1.169	-	-	-	-
Amino acid content (g)	32	40	60	80	38	48	72	96	56.0	35.0	70.1	105.1	56.0	35.0	70.1	105.1
Nitrogen content (g)	4.6	5.7	8.6	11.4	5.4	6.8	10.2	13.7	8	5	10	15	8	5	10	15
Carbohydrate content (g)	64	80	120	160	120	150	225	300	144	90	180	270	144	90	180	270
Lipid content (g)	40	50	75	100	40	50	75	100	40	25	50	75	40	25	50	75
Electrolytes:																
Sodium (mmol)	40	50	75	100	40	50	75	100	53.6	33.5	67	100.5	-	-	-	-
Potassium (mmol)	24	30	45	60	28	35	52.5	70	37.6	23.5	47	70.5	-	-	-	-
Magnesium (mmol)	2.4	3.0	4.5	6.0	3.2	4.0	6.0	8.0	4.2	2.65	5.3	7.95	-	-	-	-
Calcium (mmol)	2.4	3.0	4.5	6.0	3.2	4.0	6.0	8.0	4.2	2.65	5.3	7.95	-	-	-	-
Zinc (mmol)	0.024	0.03	0.045	0.06	0.024	0.03	0.045	0.06	0.03	0.02	0.04	0.06	-	-	-	-
Chloride (mmol)	38	48	72	96	36	45	67.5	90	48	30	60	90	-	-	-	-
Acetate (mmol)	32	40	60	80	36	45	67.5	90	48	30	60	90	-	-	-	-
Phosphate (mmol)	6.0	7.5	11.25	15.0	12	15	22.5	30	16	10	20	30	-	-	-	-

Excipients:
Citric acid monohydrate (for pH adjustment), glycerol, egg phospholipids for injection, sodium oleate, sodium hydroxide (for pH adjustment), all-rac-alpha-Tocopherol, water for injection.

Nutriflex® Omega special w/o electrolytes: Excipient(s) with known effect:
Sodium (from sodium oleate and sodium hydroxide) with max. 0.5 mmol/l in the ready to use emulsion.

THERAPEUTIC INDICATIONS Nutriflex® Omega 38/120/40 | 56/144/40 | special w/o electrolytes
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 | special w/o electrolytes 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.

METHOD OF ADMINISTRATION Nutriflex® Omega 38/120/40 | 56/144/40 | special w/o electrolytes
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 peri, Nutriflex® Omega 38/120/40, Nutriflex® Omega 56/144/40, Nutriflex® Omega special w/o 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)
- Disturbances of the electrolyte and fluid balance
- Acute pulmonary oedema
- Decompensated cardiac insufficiency
- Inadequate cellular oxygen supply

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 peri | 38/120/40 | 56/144/40 | special w/o electrolytes.

Undesirable effects are listed according to their frequencies as follows:

Common Nutriflex® Omega peri:	(≥ 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
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 Nutriflex® Omega peri: After a few days, vein irritation, phlebitis or thrombophlebitis may occur
Rare: Elevated body temperature, feeling cold, chills
Very rare: Fat overload syndrome (details see below)

Nutriflex® Omega peri: 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.

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® Omega peri | 38/120/40 | 56/144/40 | special w/o electrolytes should be discontinued immediately.

WARNINGS
Keep out of the sight and reach of children. High in sodium – see leaflet for further details.

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 34212 Melsungen, Germany

Last revision: 04/2020

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.

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

COMPOSITION

The ready-for-use emulsion for intravenous infusion contains after mixing the chamber contents:	Nutriflex® Lipid 32/64 peri				Nutriflex® Lipid 38/120 plus				Nutriflex® Lipid 56/144 special				Nutriflex® Lipid 56/144 special without electrolytes			
from the top chamber (glucose solution)	1000 ml	1250 ml	1875 ml	2500 ml	1000 ml	1250 ml	1875 ml	2500 ml	1000 ml	625 ml	1250 ml	1875 ml	1000 ml	625 ml	1250 ml	1875 ml
Glucose monohydrate (g)	70.40	88.00	132.0	176.0	132.0	165.0	247.5	330.0	158.4	99.00	198.0	297.0	158.4	99.00	198.0	297.0
equivalent to glucose (g)	64.00	80.00	120.0	160.0	120.0	150.0	225.0	300.0	144.0	90.00	180.0	270.0	144.0	90.00	180.0	270.0
Sodium dihydrogen phosphate dihydrate (g)	0.936	1.170	1.755	2.340	1.872	2.340	3.510	4.680	2.496	1.560	3.120	4.680	–	–	–	–
Zinc acetate dehydrate (mg)	5.280	6.600	9.900	13.20	5.264	6.580	9.870	13.16	7.024	4.390	8.780	13.17	–	–	–	–
from the middle chamber (fat emulsion)																
Soya-bean oil refined (g)	20.00	25.00	37.50	50.00	20.00	25.00	37.50	50.00	20.00	12.50	25.00	37.50	20.00	12.50	25.00	37.50
Medium-chain triglycerides (g)	20.00	25.00	37.50	50.00	20.00	25.00	37.50	50.00	20.00	12.50	25.00	37.50	20.00	12.50	25.00	37.50
from the bottom chamber (amino acid solution)																
Isoleucine (g)	1.872	2.340	3.510	4.680	2.256	2.820	4.230	5.640	3.284	2.053	4.105	6.158	3.284	2.053	4.105	6.158
Leucine (g)	2.504	3.130	4.695	6.260	3.008	3.760	5.640	7.520	4.384	2.740	5.480	8.220	4.384	2.740	5.480	8.220
Lysine hydrochloride (g)	2.272	2.840	4.260	5.680	2.728	3.410	5.115	6.820	3.980	2.488	4.975	7.463	3.576	2.235	4.470	6.705
equivalent to lysine (g)	1.818	2.273	3.410	4.546	2.184	2.729	4.094	5.459	3.186	1.991	3.982	5.973	3.184	1.990	3.979	5.969
Methionine (g)	1.568	1.960	2.940	3.920	1.880	2.350	3.525	4.700	2.736	1.710	3.420	5.130	2.736	1.710	3.420	5.130
Phenylalanine (g)	2.808	3.510	5.265	7.020	3.368	4.210	6.315	8.420	4.916	3.073	6.145	9.218	4.916	3.073	6.145	9.218
Threonine (g)	1.456	1.820	2.730	3.640	1.744	2.180	3.270	4.360	2.540	1.588	3.175	4.763	2.540	1.588	3.175	4.763
Tryptophan (g)	0.456	0.570	0.855	1.140	0.544	0.680	1.020	1.360	0.800	0.500	1.000	1.500	0.800	0.500	1.000	1.500
Valine (g)	2.080	2.600	3.900	5.200	2.496	3.120	4.680	6.240	3.604	2.253	4.505	6.758	3.604	2.253	4.505	6.758
Arginine (g)	2.160	2.700	4.050	5.400	2.592	3.240	4.860	6.480	3.780	2.363	4.725	7.088	3.780	2.363	4.725	7.088
Histidine hydrochloride monohydrate (g)	1.352	1.690	2.535	3.380	1.624	2.030	3.045	4.060	2.368	1.480	2.960	4.440	–	–	–	–
equivalent to histidine (g)	1.000	1.251	1.876	2.502	1.202	1.503	2.255	3.005	1.753	1.095	2.191	3.286	1.752	1.095	2.190	3.285
Alanine (g)	3.880	4.850	7.275	9.700	4.656	5.820	8.730	11.64	6.792	4.245	8.490	12.73	6.792	4.245	8.490	12.73
Aspartic acid (g)	1.200	1.500	2.250	3.000	1.440	1.800	2.700	3.600	2.100	1.313	2.625	3.938	2.100	1.313	2.625	3.938
Glutamic acid (g)	2.800	3.500	5.250	7.000	3.368	4.210	6.315	8.420	4.908	3.068	6.135	9.203	4.908	3.068	6.135	9.203
Glycine (g)	1.320	1.650	2.475	3.300	1.584	1.980	2.970	3.960	2.312	1.445	2.890	4.335	2.312	1.445	2.890	4.335
Proline (g)	2.720	3.400	5.100	6.800	3.264	4.080	6.120	8.160	4.760	2.975	5.950	8.925	4.760	2.975	5.950	8.925
Serine (g)	2.400	3.000	4.500	6.000	2.880	3.600	5.400	7.200	4.200	2.625	5.250	7.875	4.200	2.625	5.250	7.875
Sodium hydroxide (g)	0.640	0.800	1.200	1.600	0.781	0.976	1.464	1.952	1.171	0.732	1.464	2.196	–	–	–	–
Sodium chloride (g)	0.865	1.081	1.622	2.162	0.402	0.503	0.755	1.006	0.378	0.237	0.473	0.710	–	–	–	–
Sodium acetate trihydrate (g)	0.435	0.544	0.816	1.088	0.222	0.277	0.416	0.554	0.250	0.157	0.313	0.470	–	–	–	–
Potassium acetate (g)	2.354	2.943	4.415	5.886	2.747	3.434	5.151	6.868	3.689	2.306	4.611	6.917	–	–	–	–
Magnesium acetate tetrahydrate (g)	0.515	0.644	0.966	1.288	0.686	0.858	1.287	1.716	0.910	0.569	1.137	1.706	–	–	–	–
Calcium chloride dehydrate (g)	0.353	0.441	0.662	0.882	0.470	0.588	0.882	1.176	0.623	0.390	0.779	1.169	–	–	–	–
Amino acid content (g)	32	40	60	80	38	48	72	96	56.0	35.0	70.1	105.1	56.0	35.0	70.1	105.1
Nitrogen content (g)	4.6	5.7	8.6	11.4	5.4	6.8	10.2	13.7	8	5	10	15	8	5	10	15
Carbohydrate content (g)	64	80	120	160	120	150	225	300	144	90	180	270	144	90	180	270
Lipid content (g)	40	50	75	100	40	50	75	100	40	25	50	75	40	25	50	75
Electrolytes:																
Sodium (mmol)	40	50	75	100	40	50	75	100	53.6	33.5	67	100.5	–	–	–	–
Potassium (mmol)	24	30	45	60	28	35	52.5	70	37.6	23.5	47	70.5	–	–	–	–
Magnesium (mmol)	2.4	3.0	4.5	6.0	3.2	4.0	6.0	8.0	4.2	2.65	5.3	7.95	–	–	–	–
Calcium (mmol)	2.4	3.0	4.5	6.0	3.2	4.0	6.0	8.0	4.2	2.65	5.3	7.95	–	–	–	–
Zinc (mmol)	0.024	0.03	0.045	0.06	0.024	0.03	0.045	0.06	0.03	0.02	0.04	0.06	–	–	–	–
Chloride (mmol)	38	48	72	96	36	45	67.5	90	48	30	60	90	–	–	–	–
Acetate (mmol)	32	40	60	80	36	45	67.5	90	48	30	60	90	–	–	–	–
Phosphate (mmol)	6.0	7.5	11.25	15.0	12	15	22.5	30	16	10	20	30	–	–	–	–

Excipients:
Citric acid monohydrate (for pH adjustment), glycerol, egg phospholipids for injection, sodium oleate, all-rac-alpha-tocopherol, water for injections.

Nutriflex® Lipid 56/144 special without electrolytes - Excipient(s) with known effect:
Sodium (from sodium oleate) with max. 0.2 mmol/l in the ready to use emulsion.

THERAPEUTIC INDICATIONS Nutriflex® Lipid 32/64 peri
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 is indicated in adults, adolescents and children older than two years.

THERAPEUTIC INDICATIONS Nutriflex® Lipid 38/120 plus
Supply of energy, essential fatty acids, amino acids, electrolytes and fluids for parenteral nutrition of patients in states of moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated. Nutriflex® Lipid 38/120 plus is indicated in adults, adolescents and children older than two years.

THERAPEUTIC INDICATIONS Nutriflex® Lipid 56/144 special | Nutriflex® Lipid 56/144 special w/o electrolytes
Supply of energy, essential 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® Lipid 56/144 special | Nutriflex® Lipid 56/144 special w/o electrolytes is indicated in adults, adolescents and children older than two years.

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

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:

Common Nutriflex® Lipid 32/64 peri:	(≥ 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
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 Nutriflex® Lipid 32/64 peri: After a few days, vein irritation, phlebitis or thrombophlebitis may occur.
Rare: Elevated body temperature, feeling cold, chills
Very rare: Fat overload syndrome (details see below)

Nutriflex® Lipid 32/64 peri: 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.

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.

WARNINGS
Keep out of the sight and reach of children. High in sodium – see leaflet for further details.

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 34212 Melsungen, Germany

Last revision: 04/2020

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.

Product Information

Lipoplus® 200 mg/ml emulsion for infusion

COMPOSITION
1000 ml of emulsion contains:

Medium-chain triglycerides	100.0 g
Soya-bean oil, refined	80.0 g
Omega-3-acid triglycerides	20.0 g
Content of triglycerides	200 mg/ml (20%)
Content of essential fatty acids	
Linoleic acid (omega-6)	38.4 - 46.4 g/l
Alpha-linolenic acid (omega-3)	4.0 - 8.8 g/l
Eicosapentaenoic acid and docosahexaenoic acid (omega-3)	8.6 - 17.2 g/l

Excipient with known effect:
1000 ml emulsion contains 2.6 mmol sodium (as sodium hydroxide and sodium oleate).

Excipients:
Egg phospholipids for injection, glycerol, sodium oleate, ascorbyl palmitate, all-rac-α-Tocopherol, sodium hydroxide (for pH adjustment), water for injections.

THERAPEUTIC 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 hyperlipidaemia characterised by 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.

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:

Rare: (≥ 1/10000 to < 1/1000)
Very rare: (< 1/10000)
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 dosedependent 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

Skin and subcutaneous tissue disorders
Very rare: Erythema, sweating

Hepatobiliary disorders
Not known: Cholestasis

Musculoskeletal and connective tissue disorders
Rare: Back, bones, chest and lumbar region pain

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.

WARNINGS
Keep out of the sight and reach of children. For single use only. Any unused emulsion should be discarded.

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

Last revision: 07/2020

Prescription only

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

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: 01/2021

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.

Viant® powder for solution for infusion

COMPOSITION
One vial with 932 mg dry substance (powder) contains:

Retinol (Vitamin A) 0.99 mg (3300 IU) as retinol palmitate 1.82 mg
Cholecalciferol 0.005 mg equivalent to Vitamin D_3 (200 IU).
All-rac-α-tocopherol (Vitamin E) 9.11 mg.
Phytomenadione (Vitamin K_1) 0.15 mg.
Ascorbic acid (Vitamin C) 200 mg.
Thiamine (Vitamin B_1) 6.00 mg as Thiamine hydrochloride 7.63 mg.
Riboflavin (Vitamin B_2) 3.60 mg as Riboflavin sodium phosphate 4.58 mg.
Pyridoxine (Vitamin B_6) 6.00 mg as Pyridoxine hydrochloride 7.30 mg.
Cyanocobalamin (Vitamin B_{12}) 0.005 mg.
Folic acid (Vitamin B_9) 0.60 mg.
Pantothenic acid (Vitamin B_5) 15.0 mg as Dexpanthenol 14.0 mg.
Biotin (Vitamin B_7) 0.06 mg.
Nicotinamide (Vitamin B_3) 40.0 mg.

Excipient(s) with known effect:
This medicinal product contains up to 2 mmol (46 mg) sodium per vial.

Excipients: Glycine, hydrochloric acid (for pH adjustment), sodium glycocholate, soyphosphatidylcholine, sodium hydroxide (for pH adjustment).

THERAPEUTIC INDICATIONS
Parenteral vitamin substitution, when oral or enteral nutrition is impossible, insufficient or contraindicated. Viant® is indicated in adults and children aged 11 years and older.

CONTRAINDICATIONS
Hypersensitivity to the active substances or to any of the excipients listed, including soy protein and soy products or peanut protein and peanut products.

Newborns, infants and children under 11 years of age, pre-existing hypervitaminosis, severe hypercalcaemia, hypercalciuria or any treatment, disease and/or disorder that can result in severe hypercalcaemia and/or hypercalciuria (e.g. tumours, skeletal metastases, primary hyperparathyroidism, granulomatosis, etc.), combination with vitamin A or retinoids.

UNDESIRABLE EFFECTS
There have been rare reports of anaphylactoid reactions following parenteral multivitamin administration. Rare reports of anaphylactoid reactions have also been reported following large intravenous doses of thiamine mainly in patients predisposed to allergic reactions. However, the risk is negligible if thiamine is co-administered with other vitamins of the B group.

Undesirable effects are listed according to their frequencies as follows:
Not known: (cannot be estimated from the available data)

Gastrointestinal disorders
Not known: Nausea, vomiting, diarrhoea

General disorders and administration site conditions
Not known: Injection site reactions, e.g. burning sensation, rash

Immune system disorders
Not known: Hypersensitivity up to anaphylactic shock

Investigations
Not known: Transaminases increased, alanine aminotransferase increased, total bile acids increased, gamma-glutamyltransferase increased, glutamate dehydrogenase increased, blood alkaline phosphatase increased

WARNINGS
Keep out of the sight and reach of children. Contains Vitamin K.

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

Last revision: 12/2019

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.

Tracutil® concentrate for solution for infusion

COMPOSITION
Each 1 ml of the concentrate for solution for infusion contains:

	Micrograms per 1 ml
Ferrous chloride	695.8
Zinc chloride	681.5
Manganese chloride	197.9
Cupric chloride	204.6
Chromic chloride	5.3
Sodium selenite pentahydrate	7.89
Sodium molybdate dihydrate	2.42
Potassium iodide	16.6
Sodium fluoride	126.0

Each ampoule of 10 ml contains:

Trace element content	Micromoles per ampoule	Micrograms per ampoule
Iron	35	2000
Zink	50	3300
Manganese	10	550
Copper	12	760
Chromium	0.2	10
Selenium	0.3	10
Molybdenum	0.1	10
Iodine	1.0	127
Fluorine	30	570

Excipient with known effect:
Each 10 ml ampoule contains 147 micromoles (or 3.4 mg) of sodium.

List of excipients:
Hydrochloric acid (for pH-adjustment) and Water for injections.

THERAPEUTIC INDICATIONS
Tracutil® is used as part of intravenous nutrition providing a source of trace elements for adult patients.

CONTRAINDICATIONS
- Hypersensitivity to the active substances or to any of the excipients
- Pronounced cholestasis (serum bilirubin >140 mmol/l and elevated levels of gammaglutamyltransferase and alkaline phosphatase)
- Wilson's disease and disturbed iron storage (i.e. haemosiderosis or haemochromatosis)

Tracutil® is contraindicated in neonates, infants and children as its composition is not suitable for this age group.

UNDESIRABLE EFFECTS
Undesirable effects are listed according to their frequencies as follows:
Not known: (cannot be estimated from the available data)

System organ class
Immune system disorder
Not known: Anaphylactic reactions to parenterally administered iron, with possible fatal outcome.
Iodine may cause allergic reactions.

WARNINGS
Keep out of the sight and reach of children.
Only to be used if the solution is clear and colourless and the container is undamaged.

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

Last revision: 11/2012

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

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   Status of latest information: April 2020
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   Status of latest information: April 2020
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   Status of latest information: April 2020
4. SmPC Nutriflex® Lipid 56/144 special without electrolytes,
   Status of latest information: April 2020
5. SmPC Nutriflex® Omega peri,
   Status of latest information: April 2020
6. SmPC Nutriflex® Omega 38/120/40,
   Status of latest information: April 2020
7. SmPC Nutriflex® Omega 56/144/40,
   Status of latest information: April 2020
8. SmPC Nutriflex® Omega special without electrolytes,
   Status of latest information: April 2020

Lipofundin® MCT/ LCT

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The **B. Braun NuTRIscreen and NuTRIsuite App** are available on App Store

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