

Nutriflex® Omega plus

An easy bag nourishing lives



Our ready-to-use 3-chamber bag is designed to deliver moderate protein and high energy for patients in states of moderate to severe catabolism in need of parenteral nutrition.*¹

Support your moderately catabolic or chronically ill patients with Nutriflex® Omega plus.¹

Central line
administration
only



Patients (examples only)

Nutriflex® Omega plus is recommended for long-term stable patients, cancer patients without inflammation, patients with high caloric and fluid needs (2500 mL large-volume bag).¹

Suitable for children aged 2 years and older, through to adults – making it a well-suited choice across age groups.¹



Special features

User-friendly design with stable, large diameter, color-coded ports – rated easy to use in a Customer Acceptance Test (CAT)**² – helping simplify preparation and administration.



Volumes

Available in 1250 mL, 1875 mL, and 2500 mL; easy to calculate: 1 mL ≈ 1 kcal.¹



Contains Lipoplus®

A clinically proven lipid emulsion that supports fast recovery in ICU and ward patients:

- Reduces infection risk and increases infection-free days in ICU patients, compared to parenteral nutrition without Omega-3 fatty acids.³
- Shortens length of hospital stay after major abdominal surgery vs. soybean oil-based lipid emulsions.⁴
- Improves inflammation and organ function vs. MCT/LCT in patients with severe acute pancreatitis.⁵

Lipoplus® is a latest-generation IV lipid emulsion with high amounts of Omega-3 fatty acids EPA and DHA.^{1, 6, 7}

DHA=Docosahexaenoic acid; EPA=Eicosapentaenoic acid

Choose Nutriflex® Omega plus – designed to deliver moderate protein and high energy for your critically ill or chronically ill patients with high caloric or fluid needs.

Contact your local customer service for further information. (Insert your local service email, phone number, or both here.)

*When oral or enteral nutrition is impossible, insufficient or contraindicated.

**In a Customer Acceptance Test (CAT) Nutriflex® Omega bag ports were rated easy-to-use vs. Baxter (Olimel) and Fresenius Kabi (Kabiven), due to the stable and well-marked ports of B. Braun's current generation of Nutriflex®. This CAT consisted of in-depth interviews and mini focus groups conducted under standardized and controlled conditions over 2 consecutive days in Germany and the UK with 46 nurses, lab technicians and pharmacists in total. Respondents assessed various handling processes for IV port connections and injection ports in multi-chamber bags (MCBs) across different brands.²



Simplify nutrition with Nutriflex® Omega bags

Nutritional composition of Nutriflex® Omega 3-chamber bags^{1,8-10}

Content

Nutriflex® Omega	peri			38/120/40 plus			56/144/40 special ^a		
Volume (mL)	1,250	1,875	2,500	1,250	1,875	2,500	625	1,250	1,875
Amino acids (g)	40	60	80	48	72	96	35.0	70.1	105.1
Nitrogen (g)	5.7	8.6	11.4	6.8	10.2	13.7	5	10	15
Glucose (g)	80	120	160	150	225	300	90	180	270
Lipids (g)	50	75	100	50	75	100	25	50	75
Total energy (kcal)	955	1,435	1,910	1,265	1,900	2,530	740	1,475	2,215
Theoretical Osmolarity (mOsm/L)	840	840	840	1,215	1,215	1,215	1,545	1,545	1,545
Electrolytes (mmol)									
Sodium	50	75	100	50	75	100	33.5	67	100.5
Potassium	30	45	60	35	52.5	70	23.5	47	70.5
Calcium	3.0	4.5	6.0	4.0	6.0	8.0	2.65	5.3	7.95
Magnesium	3.0	4.5	6.0	4.0	6.0	8.0	2.65	5.3	7.95
Phosphate	7.5	11.25	15.0	15.0	22.5	30.0	10.0	20.0	30.0
Chloride	48	72	96	45	67.5	90	30	60	90
Acetate	40	60	80	45	67.5	90	30	60	90
Zinc	0.03	0.045	0.06	0.03	0.045	0.06	0.02	0.04	0.06

a) Nutriflex® Omega 56/144/40 special is also available in electrolyte-free versions (1330 mOsm/L).

Storage of Nutriflex® Omega^{1,8-10}

24-month shelf life at room temperature ($\leq 25^{\circ}\text{C}$). The mixed formulation can be stored for 7 days at a refrigerated temperature ($2-8^{\circ}\text{C}$) or for 2 days at 25°C .

Looking for more information on compatibility, stability, and admixing? Explore our Nutriflex® Admixing Guide for concise information on these topics.



Simple but not ordinary

Think medical nutrition simple

References

1. SPC Nutriflex® Omega plus, version 2024-01-19.
2. Alfonso JE. Drug Association Information (DIA);2024 [cited 2024 Nov 24]. Available from: <https://globalforum.diaglobal.org/issue/november-2024/#bbraun>.
3. Grau-Carmona T et al. Crit Care Med. 2015 Jan;43(1):31-9.
4. Wichmann MW et al. Crit Care Med. 2007 Mar;35(3):700-6.
5. Al-Leswas D et al. Clin Nutr. 2020 Sep;39(9):2711-2719.
6. EUROPEAN PHARMACOPOEIA Omega-3-acid triglycerides, 01/2024:1352.
7. EUROPEAN PHARMACOPOEIA Fish oil, rich in omega-3 acids 01/2023:1912.
8. SPC Nutriflex® Omega peri, version 2024-01-19.
9. SPC Nutriflex® Omega special, version 2024-01-19.
10. SPC Nutriflex® Omega special without electrolytes, version 2024-01-19.

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This material is for international use. Nutriflex® Omega may be marketed under different trade names in certain countries. Lipoplus® may be named Lipidem® in some countries. Please refer to your country-specific product information.

Mandatory information



Nutriflex® Omega 38/120/40 emulsion for infusion

Composition

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

from the top chamber (glucose solution)	in 1000 ml	in 1250 ml	in 1875 ml	in 2500 ml
Glucose monohydrate	132.0 g	165.0 g	247.5 g	330.0 g
equivalent to glucose	120.0 g	150.0 g	225.0 g	300.0 g
Sodium dihydrogen phosphate dihydrate	1.872 g	2.340 g	3.510 g	4.680 g
Zinc acetate dihydrate	5.264 mg	6.580 mg	9.870 mg	13.16 mg
from the middle chamber (fat emulsion)				
Medium-chain triglycerides	20.00 g	25.00 g	37.50 g	50.00 g
Soya-bean oil, refined	16.00 g	20.00 g	30.00 g	40.00 g
Omega-3-acid triglycerides	4.000 g	5.000 g	7.500 g	10.00 g
from the bottom chamber (amino acid solution)				
Isoleucine	2.256 g	2.820 g	4.230 g	5.640 g
Leucine	3.008 g	3.760 g	5.640 g	7.520 g
Lysine hydrochloride	2.728 g	3.410 g	5.115 g	6.820 g
equivalent to lysine	2.184 g	2.729 g	4.094 g	5.459 g
Methionine	1.880 g	2.350 g	3.525 g	4.700 g
Phenylalanine	3.368 g	4.210 g	6.315 g	8.420 g
Threonine	1.744 g	2.180 g	3.270 g	4.360 g
Tryptophan	0.544 g	0.680 g	1.020 g	1.360 g
Valine	2.496 g	3.120 g	4.680 g	6.240 g
Arginine	2.592 g	3.240 g	4.860 g	6.480 g
Histidine hydrochloride monohydrate	1.624 g	2.030 g	3.045 g	4.060 g
equivalent to histidine	1.202 g	1.503 g	2.254 g	3.005 g
Alanine	4.656 g	5.820 g	8.730 g	11.64 g
Aspartic acid	1.440 g	1.800 g	2.700 g	3.600 g
Glutamic acid	3.368 g	4.210 g	6.315 g	8.420 g
Glycine	1.584 g	1.980 g	2.970 g	3.960 g
Proline	3.264 g	4.080 g	6.120 g	8.160 g
Serine	2.880 g	3.600 g	5.400 g	7.200 g
Sodium hydroxide	0.781 g	0.976 g	1.464 g	1.952 g
Sodium chloride	0.402 g	0.503 g	0.755 g	1.006 g
Sodium acetate trihydrate	0.222 g	0.277 g	0.416 g	0.554 g
Potassium acetate	2.747 g	3.434 g	5.151 g	6.868 g
Magnesium acetate tetrahydrate	0.686 g	0.858 g	1.287 g	1.716 g
Calcium chloride dihydrate	0.470 g	0.588 g	0.882 g	1.176 g
Amino acid content [g]	38	48	72	96
Nitrogen content [g]	5.4	6.8	10.2	13.7
Carbohydrate content [g]	120	150	225	300
Lipid content [g]	40	50	75	100
Electrolytes [mmol]				
Sodium	40	50	75	100
Potassium	28	35	52.5	70
Magnesium	3.2	4.0	6.0	8.0
Calcium	3.2	4.0	6.0	8.0
Zinc	0.024	0.03	0.045	0.06
Chloride	36	45	67.5	90
Acetate	36	45	67.5	90
Phosphate	12	15	22.5	30

Excipients:

Citric acid monohydrate (for pH adjustment), glycerol, egg phospholipids for injection, sodium oleate, sodium hydroxide (for pH adjustment), all-rac- α -tocopherol, water for injection.

Therapeutic indications

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 is indicated in adults.

Contraindications

Hypersensitivity to the active substances, to egg, fish, peanut or soya protein or to any of the excipients listed. 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 38/120/40 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 Omega 38/120/40.

Undesirable effects are listed according to their frequencies as follows:

Uncommon: ($\geq 1/1,000$ to $< 1/100$)
Rare: ($\geq 1/10,000$ 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

Rare: Elevated body temperature, feeling cold, chills

Very rare: Fat overload syndrome (details 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 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 38/120/40 should be discontinued immediately.

Warnings

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

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, 34212 Melsungen, Germany

Last revision: 04/2020

Mandatory information



Nutriflex® Omega 56/144/40 emulsion for infusion

Composition

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

from the top chamber (glucose solution)	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
Glucose monohydrate	158.4 g	99.00 g	198.0 g	297.0 g
equivalent to glucose	144.0 g	90.00 g	180.0 g	270.0 g
Sodium dihydrogen phosphate dihydrate	2.496 g	1.560 g	3.120 g	4.680 g
Zinc acetate dihydrate	7.024 mg	4.390 mg	8.780 mg	13.17 mg
from the middle chamber (fat emulsion)				
Medium-chain triglycerides	20.00 g	12.50 g	25.00 g	37.50 g
Soya-bean oil, refined	16.00 g	10.00 g	20.00 g	30.00 g
Omega-3-acid triglycerides	4.000 g	2.500 g	5.000 g	7.500 g
from the bottom chamber (amino acid solution)				
Isoleucine	3.284 g	2.053 g	4.105 g	6.158 g
Leucine	4.384 g	2.740 g	5.480 g	8.220 g
Lysine hydrochloride	3.980 g	2.488 g	4.975 g	7.463 g
equivalent to lysine	3.186 g	1.991 g	3.982 g	5.973 g
Methionine	2.736 g	1.710 g	3.420 g	5.130 g
Phenylalanine	4.916 g	3.073 g	6.145 g	9.218 g
Threonine	2.540 g	1.588 g	3.175 g	4.763 g
Tryptophan	0.800 g	0.500 g	1.000 g	1.500 g
Valine	3.604 g	2.253 g	4.505 g	6.758 g
Arginine	3.780 g	2.363 g	4.725 g	7.088 g
Histidine hydrochloride monohydrate	2.368 g	1.480 g	2.960 g	4.440 g
equivalent to histidine	1.753 g	1.095 g	2.191 g	3.286 g
Alanine	6.792 g	4.245 g	8.490 g	12.73 g
Aspartic acid	2.100 g	1.313 g	2.625 g	3.938 g
Glutamic acid	4.908 g	3.068 g	6.135 g	9.203 g
Glycine	2.312 g	1.445 g	2.890 g	4.335 g
Proline	4.760 g	2.975 g	5.950 g	8.925 g
Serine	4.200 g	2.625 g	5.250 g	7.875 g
Sodium hydroxide	1.171 g	0.732 g	1.464 g	2.196 g
Sodium chloride	0.378 g	0.237 g	0.473 g	0.710 g
Sodium acetate trihydrate	0.250 g	0.157 g	0.313 g	0.470 g
Potassium acetate	3.689 g	2.306 g	4.611 g	6.917 g
Magnesium acetate tetrahydrate	0.910 g	0.569 g	1.137 g	1.706 g
Calcium chloride dihydrate	0.623 g	0.390 g	0.779 g	1.169 g
Amino acid content [g]	56.0	35.0	70.1	105.1
Nitrogen content [g]	8	5	10	15
Carbohydrate content [g]	144	90	180	270
Lipid content [g]	40	25	50	75
Electrolytes [mmol]				
Sodium	53.6	33.5	67	100.5
Potassium	37.6	23.5	47	70.5
Magnesium	4.2	2.65	5.3	7.95
Calcium	4.2	2.65	5.3	7.95
Zinc	0.03	0.02	0.04	0.06
Chloride	48	30	60	90
Acetate	48	30	60	90
Phosphate	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- α -Tocopherol, water for injection.

Therapeutic indications

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 56/144/40 is indicated in adults.

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 56/144/40 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 Omega 56/144/40.

Undesirable effects are listed according to their frequencies as follows:

Uncommon: ($\geq 1/1,000$ to $< 1/100$)
Rare: ($\geq 1/10,000$ 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

Rare: Elevated body temperature, feeling cold, chills
Very rare: Fat overload syndrome (details 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 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 56/144/40 should be discontinued immediately.

Warnings

Keep out of the sight and reach of children.

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, 34212 Melsungen, Germany

Last revision: 04/2020

Mandatory information



Nutriflex® Omega special without electrolytes emulsion for infusion

Composition

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

	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
from the top chamber (glucose solution)				
Glucose monohydrate	158.4 g	99.00 g	198.0 g	297.0 g
equivalent to glucose	144.0 g	90.00 g	180.0 g	270.0 g
from the middle chamber (fat emulsion)				
Medium-chain triglycerides	20.00 g	12.50 g	25.00 g	37.50 g
Soya-bean oil, refined	16.00 g	10.00 g	20.00 g	30.00 g
Omega-3-acid triglycerides	4.000 g	2.500 g	5.000 g	7.500 g
from the bottom chamber (amino acid solution)				
Isoleucine	3.284 g	2.053 g	4.105 g	6.158 g
Leucine	4.384 g	2.740 g	5.480 g	8.220 g
Lysine monohydrate	3.576 g	2.235 g	4.470 g	6.705 g
equivalent to lysine	3.184 g	1.990 g	3.979 g	5.969 g
Methionine	2.736 g	1.710 g	3.420 g	5.130 g
Phenylalanine	4.916 g	3.073 g	6.145 g	9.218 g
Threonine	2.540 g	1.588 g	3.175 g	4.763 g
Tryptophan	0.800 g	0.500 g	1.000 g	1.500 g
Valine	3.604 g	2.253 g	4.505 g	6.758 g
Arginine	3.780 g	2.363 g	4.725 g	7.088 g
Histidine	1.752 g	1.095 g	2.190 g	3.285 g
Alanine	6.792 g	4.245 g	8.490 g	12.73 g
Aspartic acid	2.100 g	1.313 g	2.625 g	3.938 g
Glutamic acid	4.908 g	3.068 g	6.135 g	9.203 g
Glycine	2.312 g	1.445 g	2.890 g	4.335 g
Proline	4.760 g	2.975 g	5.950 g	8.925 g
Serine	4.200 g	2.625 g	5.250 g	7.875 g
Amino acid content [g]	56.0	35.0	70.1	105.1
Nitrogen content [g]	8	5	10	15
Carbohydrate content [g]	144	90	180	270
Lipid content [g]	40	25	50	75

Excipient(s) with known effect:

Sodium (from sodium oleate and sodium hydroxide) with max. 0.5 mmol/l in the ready to use emulsion.

Excipients:

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

Therapeutic indications

Supply of energy, essential fatty acids including omega-3 and omega-6 fatty acids, amino acids, 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 special without electrolytes is indicated in adults.

Contraindications

Hypersensitivity to the active substances, to egg, fish, peanut or soya protein or to any of the excipients listed. 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 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 Omega special without electrolytes.

Undesirable effects are listed according to their frequencies as follows:

Uncommon: ($\geq 1/1,000$ to $< 1/100$)
 Rare: ($\geq 1/10,000$ 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

Rare: Elevated body temperature, feeling cold, chills
 Very rare: Fat overload syndrome (details 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 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 special without electrolytes should be discontinued immediately.

Warnings

Keep out of the sight and reach of children.

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, 34212 Melsungen, Germany

Last revision: 04/2020

Mandatory information



Nutriflex® Omega peri emulsion for infusion

Composition

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

from the top chamber (glucose solution)	1000 ml	1250 ml	1875 ml	2500 ml
Glucose monohydrate	70.40 g	88.00 g	132.0 g	176.0 g
equivalent to glucose	64.00 g	80.00 g	120.0 g	160.0 g
Sodium dihydrogen phosphate dihydrate	0.936 g	1.170 g	1.755 g	2.340 g
Zinc acetate dihydrate	5.280 mg	6.600 mg	9.900 mg	13.20 mg
from the middle chamber (fat emulsion)				
Medium-chain triglycerides	20.00 g	25.00 g	37.50 g	50.00 g
Soya-bean oil, refined	16.00 g	20.00 g	30.00 g	40.00 g
Omega-3-acid triglycerides	4.000 g	5.000 g	7.500 g	10.00 g
from the bottom chamber (amino acid solution)				
Isoleucine	1.872 g	2.340 g	3.510 g	4.680 g
Leucine	2.504 g	3.130 g	4.695 g	6.260 g
Lysine hydrochloride	2.272 g	2.840 g	4.260 g	5.680 g
equivalent to lysine	1.818 g	2.273 g	3.410 g	4.546 g
Methionine	1.568 g	1.960 g	2.940 g	3.920 g
Phenylalanine	2.808 g	3.510 g	5.265 g	7.020 g
Threonine	1.456 g	1.820 g	2.730 g	3.640 g
Tryptophan	0.456 g	0.570 g	0.855 g	1.140 g
Valine	2.080 g	2.600 g	3.900 g	5.200 g
Arginine	2.160 g	2.700 g	4.050 g	5.400 g
Histidine hydrochloride monohydrate	1.352 g	1.690 g	2.535 g	3.380 g
equivalent to histidine	1.000 g	1.251 g	1.876 g	2.502 g
Alanine	3.880 g	4.850 g	7.275 g	9.700 g
Aspartic acid	1.200 g	1.500 g	2.250 g	3.000 g
Glutamic acid	2.800 g	3.500 g	5.250 g	7.000 g
Glycine	1.320 g	1.650 g	2.475 g	3.300 g
Proline	2.720 g	3.400 g	5.100 g	6.800 g
Serine	2.400 g	3.000 g	4.500 g	6.000 g
Sodium hydroxide	0.640 g	0.800 g	1.200 g	1.600 g
Sodium chloride	0.865 g	1.081 g	1.622 g	2.162 g
Sodium acetate trihydrate	0.435 g	0.544 g	0.816 g	1.088 g
Potassium acetate	2.354 g	2.943 g	4.415 g	5.886 g
Magnesium acetate tetrahydrate	0.515 g	0.644 g	0.966 g	1.288 g
Calcium chloride dihydrate	0.353 g	0.441 g	0.662 g	0.882 g
Electrolytes [mmol]				
Sodium	40	50	75	100
Potassium	24	30	45	60
Magnesium	2.4	3.0	4.5	6.0
Calcium	2.4	3.0	4.5	6.0
Zinc	0.024	0.03	0.045	0.06
Chloride	38	48	72	96
Acetate	32	40	60	80
Phosphate	6.0	7.5	11.25	15.0
Amino acid content [g]	32	40	60	80
Nitrogen content [g]	4.6	5.7	8.6	11.4
Carbohydrate content [g]	64	80	120	160
Lipid content [g]	40	50	75	100

Excipients:

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

Therapeutic indications

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.

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 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 Omega peri.

Undesirable effects are listed according to their frequencies as follows:

Common: ($\geq 1/100$ to $< 1/10$)

Uncommon: ($\geq 1/1,000$ to $< 1/100$)

Rare: ($\geq 1/10,000$ 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: 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)

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 should be discontinued immediately.

Warnings

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

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, 34212 Melsungen, Germany

Last revision: 04/2020

Mandatory 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, 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: ($\geq 1/10,000$ 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

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.

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, 34212 Melsungen, Germany

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