Nutriflex® Omega insights

Nutriflex® Omega – simply balanced

Emerging evidence on protein in clinical nutrition

B BRAUN
SHARING EXPERTISE

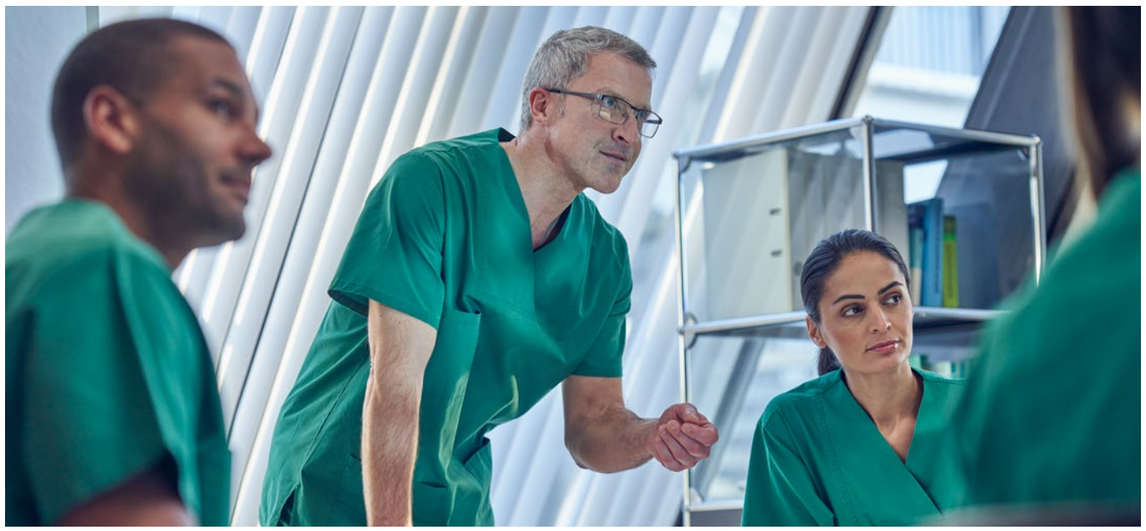
Addressing the challenges of nutrition

Despite long-standing recommendations for high-dose protein administration in critically ill patients, emerging clinical evidence challenges this practice.

Recent randomized controlled trials (RCTs) suggest that early, aggressive protein administration may not offer the expected benefits – and could even be detrimental – reinforcing the need to reassess current nutritional strategies in critical care to adopt a more nuanced and evidence-based approach. [1–4]

Key insights on latest protein findings in critical care

- High protein intake (>1.2 g/kg/d) was not associated with improved clinical outcomes compared to standard intake and may negatively impact the prognosis of critically ill patients. [1–4] Notably, this finding remained consistent even among overweight patients. [5]
- The EFFORT Protein Trial demonstrated that higher protein dosing (≥2.2 compared to ≤1.2 g/kg/d) did not improve time to discharge alive from hospital in critically ill patients. [1]
- Furthermore, the study found that higher protein doses may even be harmful in critically ill patients with acute kidney injury and higher baseline organ failure scores. Therefore, protein administration should be considered with particular caution in these patients. [1]



High protein – Hype vs. evidence

Multiple randomized controlled trials (RCTs) have failed to confirm the expected benefits of higher protein intake – whether given alone or alongside physical activity or energy supplementation. These findings are further supported by post hoc subgroup analyses and meta-analyses. [1–3]

EFFORT, PRECISe and TARGET are among the largest RCTs conducted to date on protein dosing in critically ill patients [1–3]

Multiple RCTs

EFFORT Protein
Heyland DK et al. 2023 [1]
Effect of higher protein dosing in mechanically ventilated critically ill patients with high nutritional risk

PRECISe
Bels JLM et al. 2024 [2]
Effect of high vs. standard protein provision on functional recovery in people with critical illness

TARGET Protein
Summers MJ et al. 2025 [3]
Augmented enteral protein during critical illness

NUTRIREA-3
Reignier J et al. 2023 [6]
Low vs. standard calorie and protein feeding in ventilated adults with shock

Subgroups / Meta-analyses

Stoppe C et al. 2023
Post-hoc analysis EFFORT [4]
Impact of higher protein dosing on outcomes in critically ill patients with acute kidney injury

Haines RW et al. 2024
Exploratory secondary Bayesian analyses EFFORT [7]
Effect of high protein dosing

Lee ZY et al. 2024
Updated systematic review and meta-analysis of RCTs [9]
Effects of higher vs. lower protein delivery

Tweel LE et al. 2025
Post-hoc analysis EFFORT [5]
Comparison of high vs. usual protein dosing in critically ill patients with obesity

Schouteden E et al. 2025
Pre-planned Bayesian analysis of PRECISe [8]
Impact of enteral protein provision on functional recovery following intensive care admission

Qin Y et al. 2024
Systematic review and meta-analysis of RCTs [10]
Comparison of higher vs. lower doses of protein supplementation

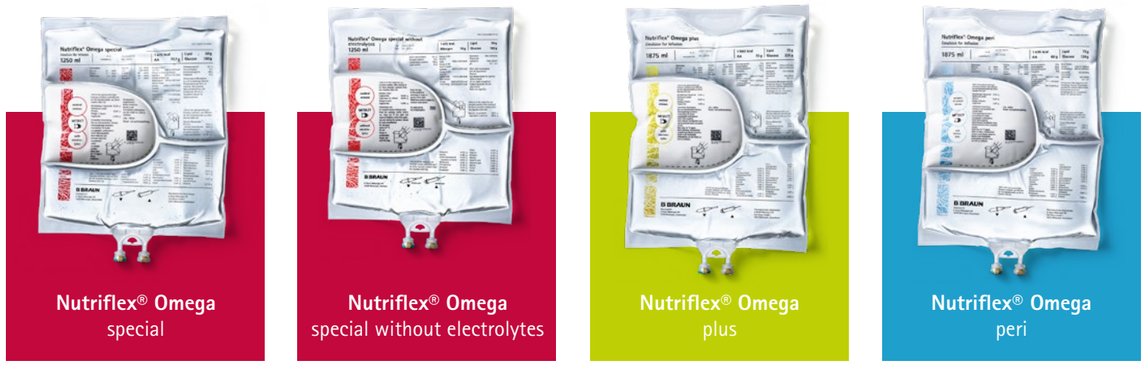
Progressive feeding – Tailored nutrition delivery

In light of these recent findings, experts recommend progressive feeding strategies for critically ill patients – starting with lower initial protein and energy intake, gradually increasing as the patient stabilizes. [11]

Key findings on progressive feeding

- Progressive feeding, starting with lower protein and energy in the early phase of critical illness, has been shown to be an expert-recommended approach in critically ill patients. [11]
- Appropriate protein delivery is suggested to range from 1.2–1.3 g/kg/d,[2] while appropriate energy delivery may range from 5–20 kcal/kg/d during ICU stay. [1]
- Prescribing 1.2 g/kg protein per day and aiming to achieve 80 % of this target is considered a practical and evidence-based strategy for managing nutrition in critically ill patients. [1]
- These protein targets align with the lower end of the ASPEN 2022 recommendations [1,12] as well as with the 1.3 g/kg/d recommended by the ESPEN 2023 guidelines. [1,13]
- In addition, ESPEN guidelines recommend that protein should be administered progressively during critical illness. [13]

Nutriflex® Omega – Protein and energy support in line with patient recovery



Nutriflex® Omega supports critically ill patients from the early phase of critical illness and beyond. Its nutritional composition aligns with a progressive nutrition approach, as supported by current clinical guidelines and the latest evidence. [14–17]

Nutriflex® Omega special – Simply balanced

Nutriflex® Omega special provides balanced PN for critically ill patients, helping to meet protein and energy needs in line with clinical guidelines. [12–15]

Nutriflex® Omega special

Provides nutritional support for critically ill patients in states of moderate to severe catabolism throughout the entire ICU stay and beyond. [14]

Delivers a **balanced supply of protein** (0.2–1.2 g/kg/d) and energy (5–25 kcal/kg/d), helping to meet the individual nutritional needs of critically ill patients throughout their recovery journey. [14]

Available in **multiple bags sizes** – 625 mL, 1250 mL and 1875 mL – to support individual patient needs and progressive feeding across all stages of care. [14]

625 mL bag is well-suited for **initiating progressive feeding** or providing supplemental nutrition. [14]

Available **with or without electrolytes** for individual electrolyte management. [14,15]

Contains Lipoplus® – a latest-generation IV lipid emulsion enriched with Omega-3 fatty acids (EPA and DHA), to support fast recovery in ICU and ward patients. [14,15,18]

DHA=Docosahexaenoic acid; EPA=Eicosapentaenoic acid

Use of Nutriflex® Omega special in a critically ill patient (example case)*[14]

Peter | 55 years old | 75 kg – **day 3** and **day 6** of feeding

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Progressive feeding algorithm[11]
Energy 5–10 kcal/kg
Protein 0.2–0.6 g/kg

Individual patient requirements
Energy 375–750 kcal/d
Protein 15–45 g/d

Nutritional requirements	Lower end	Middle / high end	Higher end
Nutriflex® Omega special	**625 mL**	**625 mL**	**1250 mL**
Infusion rate	12 mL/hr	26 mL/hr	30 mL/hr
Energy	341 kcal/d	740 kcal/d	849 kcal/d
Protein	16.0 g/d	35.0 g/d	40.3 g/d

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Progressive feeding algorithm[11]
Energy 15–20 kcal/kg
Protein 0.8–1.0 g/kg

Individual patient requirements
Energy 1125–1500 kcal/d
Protein 60–75 g/d

Nutritional requirements	Lower end	Higher end
Nutriflex® Omega special	**1250 mL**	**1250 mL**
Infusion rate	45 mL/hr	52 mL/hr
Energy	1274 kcal/d	1475 kcal/d
Protein	60.5 g/d	70.1 g/d

Nutriflex® Omega special recommended for (examples only):[14]

- Cancer, surgery (including GI surgery), acute injuries and major burns, or supplemental parenteral nutrition via small volume bags
- Suitable for children aged 2 years and older, through to adults – making it an appropriate choice across age groups

Nutriflex® Omega special delivers both flexibility and precision — by simply adjusting the administration rate, it meets both lower and upper ends of calculated nutritional needs.[14,15]

Nutriflex® Omega special: Balanced nutrition therapy for critically ill patients.[14,15]
Contact your local customer service for further information.

*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:

	in 1000 ml	in 1250 ml	in 1875 ml	in 2500 ml
from the top chamber (glucose solution)				
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: (≥ 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
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

Nutriflex® Omega peri emulsion for infusion

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

	1000 ml	1250 ml	1875 ml	2500 ml
from the top chamber (glucose solution)				
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: (≥ 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: 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

Nutriflex® Omega 56/144/40 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
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: (≥ 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
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

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: (≥ 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
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

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: (≥ 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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