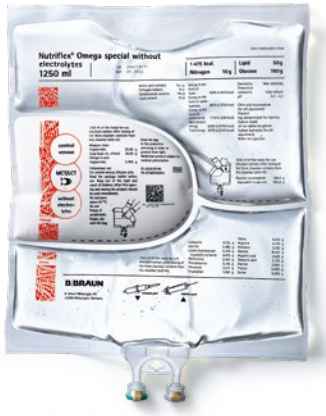
# Nutriflex® Omega special without electrolytes

## An easy bag nourishing lives

B|BRAUN
SHARING EXPERTISE



**Our ready-to-use 3-chamber bag is designed to deliver elevated protein and energy for patients in states of moderate to severe catabolism in need of parenteral nutrition, where individualized electrolyte administration is required.*[1]**

**Support your critically ill patients during their entire ICU journey and beyond with Nutriflex® Omega special without electrolytes.[1]**

Central line administration only

### Patients (examples only)

Nutriflex® Omega special without electrolytes is recommended for cancer, surgery (including GI surgery), acute injuries and major burns with electrolyte imbalances, or requiring intradialytic parenteral nutrition (IDPN).[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 and 1875 mL, also with electrolytes (625 mL, 1250 mL, and 1875 mL).[1,3]

### 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.[4]
- Shortens length of hospital stay after major abdominal surgery vs. soybean oil-based lipid emulsions.[5]
- Improves inflammation and organ function vs. MCT/LCT in patients with severe acute pancreatitis.[6]

**Lipoplus® is a latest-generation IV lipid emulsion with high amounts of Omega-3 fatty acids EPA and DHA.[1,7,8]**

DHA=Docosahexaenoic acid; EPA=Eicosapentaenoic acid

**Choose Nutriflex® Omega special without electrolytes – designed to deliver elevated protein and energy levels for your critically ill patients in need of individualized electrolyte therapy.[1]**
**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[1,3,9,10]

**Content**

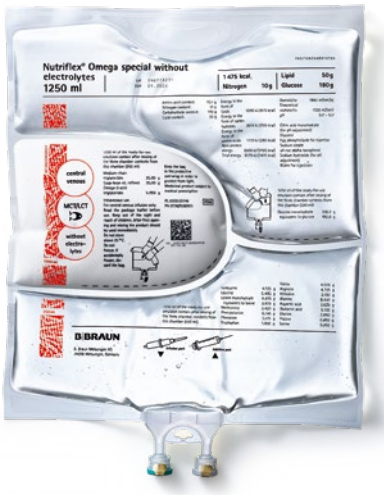
| Nutriflex® Omega | peri | | | 38/120/40 plus | | | 56/144/40 special[a] | | |
|---|---|---|---|---|---|---|---|---|---|
| Volume (mL) | 1,250 | 1,875 | 2,500 | 1,250 | 1,875 | 2,500 | 625 | 1,250 | 1,875 |
| Amino acids (g) | 40 | 60 | 80 | 48 | 72 | 96 | 35.0 | 70.1 | 105.1 |
| Nitrogen (g) | 5.7 | 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[1,3,9,10]

**24-month shelf life** at room temperature (≤25°C). The mixed formulation can be stored for 7 days at a refrigerated temperature (2–8°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.




# References


1. SPC Nutriflex® Omega special without electrolytes, 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. SPC Nutriflex® Omega special, version 2024-01-19.
4. Grau-Carmona T et al. Crit Care Med. 2015 Jan;43(1):31–9.
5. Wichmann MW et al. Crit Care Med. 2007 Mar;35(3):700–6.
6. Al-Leswas D et al. Clin Nutr. 2020 Sep;39(9):2711–2719.
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8. EUROPEAN PHARMACOPOEIA Fish oil, rich in omega-3 acids 01/2023:1912.
9. SPC Nutriflex® Omega peri, version 2024-01-19.
10. SPC Nutriflex® Omega plus, version 2024-01-19.

# 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: (≥ 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

## 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.

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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:

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Uncommon: Nausea, vomiting

***Metabolism and nutrition disorders***
Uncommon: Loss of appetite

***Hepatobiliary disorders***
Not known: Cholestasis

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Rare: Erythema, sweating

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Rare: Pain in the back, bones, chest and lumbar region

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Rare: Elevated body temperature, feeling cold, chills
Very rare: Fat overload syndrome (details see below)

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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**
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**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:

| | 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 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

# 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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