NAME OF THE MEDICINAL PRODUCT

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 equivalent to glucose	132.0 g 120.0 g	165.0 g 150.0 g	247.5 g 225.0 g	330.0 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)	**in 1000 ml**	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
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)	**in 1000 ml**	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
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 equivalent to lysine	2.728 g 2.184 g	3.410 g 2.729 g	5.115 g 4.094 g	6.820 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 equivalent to histidine	1.624 g 1.202 g	2.030 g 1.503 g	3.045 g 2.254 g	4.060 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

	in 1000 ml	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
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]	**in 1000 ml**	**in 1250 ml**	**in 1875 ml**	**in 2500 ml**
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-alpha-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 < 1/1000)
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.

B. Braun Melsungen AG, 34212 Melsungen, Germany, 04/2020

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