

NAME OF THE MEDICINAL PRODUCT

Nutriflex Lipid 32/64 peri Emulsion for infusion

COMPOSITION

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

from the top chamber (glucose solution)	in 1000 ml	in 1250 ml	in 1875 ml	in 2500 ml
Glucose monohydrate equivalent to glucose	70.40 g 64.00 g	88.00 g 80.00 g	132.0 g 120.0 g	176.0 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)	in 1000 ml	in 1250 ml	in 1875 ml	in 2500 ml
Soya-bean oil, refined	20.00 g	25.00 g	37.50 g	50.00 g
Medium-chain triglycerides	20.00 g	25.00 g	37.50 g	50.00 g

from the bottom chamber (amino acid solution)	in 1000 ml	in 1250 ml	in 1875 ml	in 2500 ml
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 equivalent to lysine	2.272 g 1.818 g	2.840 g 2.273 g	4.260 g 3.410 g	5.680 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 equivalent to histidine	1.352 g 1.000 g	1.690 g 1.251 g	2.535 g 1.876 g	3.380 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]	in 1000 ml	in 1250 ml	in 1875 ml	in 2500 ml
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

	in 1000 ml	in 1250 ml	in 1875 ml	in 2500 ml
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, all-rac-alpha-tocopherol, water for injections.

THERAPEUTIC INDICATIONS

Supply of energy, essential fatty acids, amino acids, electrolytes and fluids for parenteral nutrition of patients in states of mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.

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

CONTRAINDICATIONS

Hypersensitivity to the active substances, to egg, peanut or soya protein or to any of the excipients; inborn errors of amino acid metabolism; severe hypertriglyceridaemia (≥ 1000 mg/dl or 11.4 mmol/l); severe coagulopathy; hyperglycaemia not responding to insulin doses of up to 6 units insulin/hour; acidosis; intrahepatic cholestasis; severe hepatic insufficiency; severe renal insufficiency in absence of

renal replacement therapy; aggravating haemorrhagic diatheses; acute thrombo-embolic events, lipid embolism.

On account of its composition, Nutriflex Lipid 32/64 peri must not be used in newborn infants, infants and toddlers under 2 years of age.

General contraindications to parenteral nutrition include unstable circulatory status with vital threat (states of collapse and shock); acute phases of cardiac infarction and stroke; unstable metabolic condition (e.g. severe postaggression syndrome, coma of unknown origin); inadequate cellular oxygen supply; disturbances of the electrolyte and fluid balance; acute pulmonary oedema; decompensated cardiac insufficiency.

UNDESIRABLE EFFECTS

Under conditions of correct use, in terms of dosing monitoring, observation of safety restrictions and instructions, undesirable effects may still occur. The following listing includes a number of systemic reactions that may be associated with the use of Nutriflex Lipid 32/64 peri.

Undesirable effects are listed according to their frequencies as follows:

Common: ($\geq 1/100$ to $< 1/10$)
Uncommon: ($\geq 1/1\ 000$ to $< 1/100$)
Rare: ($\geq 1/10\ 000$ to $< 1/1000$)
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

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 Lipid 32/64 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.

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