

## NAME OF THE MEDICINAL PRODUCT

Nutriflex Lipid 56/144 special Emulsion for infusion

## COMPOSITION

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

<b><i>from the top chamber (glucose solution)</i></b>	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
Glucose monohydrate equivalent to glucose	158.4 g 144.0 g	99.00 g 90.00 g	198.0 g 180.0 g	297.0 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

<b><i>from the middle chamber (fat emulsion)</i></b>	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
Soya-bean oil, refined	20.00 g	12.50 g	25.00 g	37.50 g
Medium-chain triglycerides	20.00 g	12.50 g	25.00 g	37.50 g

<b><i>from the bottom chamber (amino acid solution)</i></b>	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
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 equivalent to lysine	3.980 g 3.186 g	2.488 g 1.991 g	4.975 g 3.982 g	7.463 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 equivalent to histidine	2.368 g 1.753 g	1.480 g 1.095 g	2.960 g 2.191 g	4.440 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

<b>Electrolytes [mmol]</b>	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
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

	in 1000 ml	in 625 ml	in 1250 ml	in 1875 ml
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

*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 moderate to severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.

Nutriflex Lipid 56/144 special 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 ( $\geq 1000$  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 56/144 special 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 56/144 special.

Undesirable effects are listed according to their frequencies as follows:

Uncommon: ( $\geq 1/1\ 000$  to  $< 1/100$ )  
Rare: ( $\geq 1/10\ 000$  to  $< 1/1000$ )  
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 Lipid 56/144 special 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**