

## NAME OF THE MEDICINAL PRODUCT

[Invented name] 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 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

<b><i>from the middle chamber (fat emulsion)</i></b>	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

<b><i>from the bottom chamber (amino acid solution)</i></b>	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 2.255 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

<b>Electrolytes [mmol]</b>	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

	in 1000 ml	in 1250 ml	in 1875 ml	in 2500 ml
Amino acid content	38	48	72	96
Nitrogen content	5.4	6.8	10.2	13.7
Carbohydrate content [g]	120	150	225	300
Lipid content	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 moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.

[Invented name] 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, this medicinal product 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 [Invented name].

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: (frequency 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***

Uncommon: Loss of appetite

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

**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 this medicinal product should be discontinued immediately.

## **WARNINGS**

Keep out of the sight and reach of children. High in sodium – see leaflet for further details.

## **NOTE**

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, 09/2023**