NAME OF THE MEDICINAL PRODUCT

Lipofundin MCT 20% Emulsion for Infusion

COMPOSITION

1000 ml of emulsion contain:

Soya-bean oil, refined	100.0 g
Medium-chain triglycerides (MCT)	100.0 g

Essential fatty acid content per 1000 ml:

Linoleic acid	48.0 – 58.0 g
α-Linolenic acid	5.0 – 11.0 g

Excipient(s) with known effect:
Lipofundin MCT 20% contains less than 1 mmol (23 mg) sodium per litre.

Excipients:
Glycerol: 25.0 g/l, egg phospholipids for injection: 12.0 g equivalent to (3-sn-Phosphatidyl)cholin 7.2 g (egg lecithin 12.0 g/l), all-rac-α-Tocopherol: 170 ($\pm$ 40) mg/l, sodium oleate (for pH-adjustment), water for injections.

THERAPEUTIC INDICATIONS

Energy supply including a rapidly utilisable lipid component (MCT); supply of essential fatty acids as part of complete parenteral nutrition.

CONTRAINDICATIONS

Hypersensitivity to egg or soya-bean protein, soya-bean or peanut products or to any of the active substances or the excipients.
Severe hyperlipidemia; severe coagulopathy; severe hepatic insufficiency; intrahepatic cholestasis; severe renal insufficiency in absence of renal replacement therapy; acute thromboembolic events; fat embolism; aggravating hemorrhagic diatheses; metabolic acidosis.

General contraindications to parenteral nutrition:
Unstable circulatory status with vital threat (states of collapse and shock); unstable metabolic conditions (e.g. severe post-aggression syndrome, severe sepsis, coma of unknown origin); acute phase of

myocardial infarction or stroke; uncorrected disorders of fluid and electrolyte balance, such as hypokalemia and hypotonic dehydration; decompensated cardiac insufficiency; acute pulmonary edema.

UNDESIRABLE EFFECTS

The following listing includes a number of systemic adverse reactions that may be associated with the use of Lipofundin MCT. 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:

Very rare: (<1/10 000)
Not known: (cannot be estimated from the available data)

Blood and lymphatic system disorders
Very rare: Hypercoagulability
Not known: Leucopenia, thrombocytopenia

Immune system disorders
Very rare: Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial edema)

Metabolism and nutrition disorders
Very rare: Hyperlipidemia, hyperglycemia, metabolic acidosis, ketoacidosis. The frequency of these adverse reactions is dose-dependent and may be higher under conditions of absolute or relative overdose.

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

Hepatobiliary disorders
Not known: Cholestasis

Skin and subcutaneous tissue disorders
Very rare: Erythema, sweating

Musculoskeletal and connective tissue disorders
Very rare: Pain in the back, bones, chest and lumbar region

General disorders and administration site conditions
Very rare: Increased body temperature, feeling cold, chills, fat overload syndrome (see below).

If adverse reactions occur, the infusion of Lipofundin MCT must be stopped or, if necessary, continued at a reduced dosage.

If the infusion is restarted, the patient must be carefully monitored, especially at the beginning, and serum triglycerides should be determined at short intervals.

Information on particular undesirable effects

Nausea, vomiting, lack of appetite and hyperglycemia are symptoms related to conditions constituting an indication for parenteral nutrition and may sometimes be associated with parenteral nutrition.

Fat overload syndrome
Overdose of lipid emulsion or impaired capacity to eliminate triglycerides can lead to “fat overload syndrome”. Possible signs of metabolic overload must be observed.
The cause may be a genetic predisposition (individually different metabolism) or the lipid metabolism may be impaired by ongoing or previous diseases.
This syndrome may also appear during severe hypertriglyceridemia, 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 hyperlipidemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anemia, leucopenia, thrombocytopenia, coagulation disorder, hemolysis 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 Lipofundin MCT must be discontinued immediately.

WARNINGS

Keep out of the sight and reach of children. Shake gently prior to use. Use only if the emulsion is homogenous and milky-white after shaking and the container is undamaged. For single use only. Discard unused contents.

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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