Lipofundin® MCT/LCT 20 % emulsion for infusion

Composition

1000 ml infusion for intravenous use contains:

- Sunflower oil 550 g
- Emulsifying wax 20 g
- Purified water 430 g

Medium-chain triglycerides (MCT) 1000 g

Energy content: 48.6 – 50.0 g lipid

Linoleic acid ≤ 0.4 g lipid

Lauric acid ≥ 9.8 g lipid

Pharmacotherapeutic group

Pharmacotherapeutic group: Nutritional supplements

ATC code: B05A D02

Indications

- Energy supply including a readily available lipid component (MCT)
- Supply of essential fatty acids as part of total parenteral nutrition

Contraindications

- Hypersensitivity to egg or soya-bean protein, egg white in peanut or palm kernel oil and other components of the active substances or the excipients.
- Severe hyperlipidaemia
- Severe hepatic insufficiency
- Severe hepatic failure
- Severe renal insufficiency in absence of renal replacement therapy
- Acute pulmonary events
- Fat embolism
- Thrombophlebitis/diathesis
- Metabolisches Abendessen
- Severe hyperlipidaemia in the paediatric population

Special warnings and precautions for use

The triglyceride concentration should be regularly monitored during the infusion of Lipofundin MCT/LCT.

Depending on the patient’s metabolic condition, occasional hypertriglyceridaemia may occur if the plasma triglyceride concentration increases above 5 mmol/l. In such cases, the dose of Lipofundin MCT/LCT should immediately be reduced in case of acute consequences of an elevated triglyceride level, e.g. fever, dyspnoea, renal dysfunctions.

Even though triglycerides cause metabolic acidosis, it is therefore recommended to infuse an adequate quantity of carboxylic acids and amines along with the fat emulsion.

For patients requiring complete parenteral nutrition, complete amino-acid solutions, essential fatty acids, vitamins, minerals, and trace elements are required. Also, adequate total fluid intake must be ensured.

Maintenance with insulin-dependent diabetics might lead to breakthrough of the keto-trajectories or to precipitation of diabetes ketoses ("formaketylyse“ and "Instructions for storage / use / handling“), both resulting in a high risk of insulin reactions.

In infusions with higher lipid concentration (e.g. Lipofundin MCT/LCT 20%), the risk of emulsification (phlogopoph) is in order to lower than in lower concentrated lipid emulsions. This ensures a feasible plasma clearance of triglycerides, phospholipids, free fatty acids as well as the pathological lipid profile in the patient’s blood. Therefor higher concentrated lipid emulsions like Lipofundin MCT/LCT 20% should be preferred over lower concentrated lipid emulsions.

Children and adolescents

Caution should be exercised in patients suffering from further diseases, associated with increased risk of hyperlipidaemia that may frequently be associated with advanced age.

Patients with impaired lipid metabolism

Lipofundin MCT/LCT should be cautiously administered to patients with disturbances of lipid metabolism, e.g. renal insufficiency, diabetes mellitus, hypercholesterolaemia, impaired hepatic function, hypothyroidism (both hyperlipidaemic and normo-), and epilepsy.

If Lipofundin MCT/LCT is administered to patients with these conditions, close monitoring of serum triglycerides is necessary. The dose should be adjusted to the metabolic requirements and the presence of hyperlipidaemia. 12 hours after lipid administration also indicates a distance of lipid metabolism.

Pregnancy/Childbirth

Precautions

Pregnancy and lactation

There is no or limited amount of data from the use of Lipofundin MCT/LCT in pregnant women. Animal data are not available and therefore are not to be considered as reflecting potential or probable human effects.

Hypersensitivity reactions to an ingredient of Lipofundin MCT/LCT (e.g. Soybean oil, egg lecithin) are extremely rare. However, it cannot be excluded that reactions to excipients like soya-bean oil or egg lecithin may occur. When lipids melt, it is not expected to interfere in a biological way with the serum triglycerides.

Eggs and soya are statements regarding the safety of ovulation and fertility. However, concerning the potential to interfere with certain laboratory tests (such as bilirubin, bilirubin, phospholipids and, protein, haemoglobin or leucocytes), both resulting in a direct correlation with the calculated coagulation parameters.

The serum triglyceride concentration should be regularly monitored during the infusion of Lipofundin MCT/LCT. If the plasma triglyceride concentration during infusion exceeds 4.5 mmol/l, lipid administration should be corrected before the start of infusion.

In case of excessive lipid administration, fluid, hypokalaemia, acidosis, fluid-volunteers, cardiac events, cardiopulmonary arrest, systemic events and anaphylaxis could be expected. In such cases, the dose of Lipofundin MCT/LCT should immediately be reduced in case of acute consequences of an elevated triglyceride level, e.g. fever, dyspnoea, renal dysfunctions.

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**Undesirable effects**

The following listing includes a number of systemic adverse reactions that may be associated with the use of Lipofundin MCT/LCT, taking the conditions of correct use, in terms of dosing, monitoring, storage, safe handling and instructions, most of them are very rare (< 1/10,000).

**High frequencies**

- **Hypersensitivity**
  - General disorders and administration site conditions
  - Nervous system disorders
  - Respiratory, thoracic and mediastinal disorders
  - Skin and subcutaneous tissue disorders
  - General disorders and administration site conditions

- **Nausea, vomiting, loss of appetite**
  - Gastrointestinal disorders

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- **Hyperglycaemia**, **hyperkalaemia**, **metabolic acidosis**
  - Metabolism and nutrition disorders

- **Hyperlipidaemia**
  - Metabolism and nutrition disorders

- **Headache, drowsiness**
  - Nervous system disorders

- **Hypercoagulability**
  - Blood and lymphatic system disorders

- **Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema)**
  - Immune system disorders

- **Cardiovascular disorders**
  - Vascular disorders

**Mild frequencies**

- **Hypertension or hypotension**
  - Respiratory, thoracic and mediastinal disorders

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  - Respiratory, thoracic and mediastinal disorders

**Very rare (< 1/10,000)**

- **Pain in the back, bones, chest and lumbar region**
  - Musculoskeletal and connective tissue disorders

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- **Erythema, sweating**
  - Skin and subcutaneous tissue disorders

- **Leucopenia, thrombocytopenia**
  - Blood and lymphatic system disorders

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- **Cholestasis**
  - Hepatobiliary disorders

**Not known**

- **Hyperlipidaemia, hyperglycaemia, metabolic acidosis**
  - Metabolism and nutrition disorders

**Listing of undesirable effects**

Undesirable effects are listed according to their frequencies as follows:

- **Very common** (≥ 1/10)
- **Uncommon** (≥ 1/1,000 to < 1/100)
- **Rare** (≥ 1/10,000 to < 1/1,000)
- **Very rare** (< 1/10,000)
- **Not known** (frequency cannot be estimated from the available data)

**General disorders and administration site conditions**

- **Very rare**: Pain in the back, bones, chest and lumbar region. See section "Undesirable effects".

**Treatment**

Immediate cessation of infusion is indicated for overdose. Other therapeutic measures will depend on the particular symptoms and their severity. When the infusion is recommenced after symptoms have declined, it is recommended that the infusion rate be raised gradually with monitoring at frequent intervals.

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**Hypersensitivity**

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**Cardiovascular disorders**

- **Hypertension or hypotension**
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**Skin and subcutaneous tissue disorders**

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**Musculoskeletal and connective tissue disorders**

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**General disorders and administration site conditions**

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**Hepatobiliary disorders**

- **Nausea, vomiting, loss of appetite**
  - Gastrointestinal disorders

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