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Directions for Use

B. Braun Melsungen AG · D-34209 Melsungen, Germany

Lipofundin® MCT/LCT 10%

Composition

1000 ml of emulsion contain

Soya-bean Oil	50.0 g
Medium-chain Triglycerides	50.0 g

Glycerol, egg lecithin, all-rac-α-tocopherol, sodium oleate, water for injections

Content of essential fatty acids:

Linoleic acid	24.0 - 29.0 g/l
α-Linolenic acid	2.5 - 5.5 g/l
Caloric value:	4280 kJ/l = 1022 kcal/l
Theoretical osmolarity	345 mOsm/l
Titration acidity or alkalinity (to pH 7.4)	< 0.5 mmol/l
pH	6.5 - 8.8

Pharmaceutical form

Emulsion for infusion

Pharmaco-therapeutic group

Fat emulsion for calorie supply and supply of essential fatty acids

Indications

Calorie supply including a readily metabolisable fat component (MCT);

Supply of essential fatty acids and fluid in the setting of total parenteral nutrition.

Contraindications

Lipofundin® MCT/LCT 10% must not be administered in the following conditions:

Severe blood coagulation disorders, states of shock and collapse, acute thrombo-embolism, fat embolism, severe septicaemia accompanied by acidosis and hypoxia, acute phases of myocardial infarction and stroke, keto-acidotic coma, decompensated diabetic metabolism or unstable metabolism.

The administration of Lipofundin® MCT/LCT 10% is also contra-indicated if serum triglycerides accumulate in the following conditions:

Disorders of lipid metabolism, liver diseases, disorders of the reticulo-endothelial system, haemorrhagic necrotising pancreatitis.

General contra-indications for parenteral nutrition:

Acidoses of various origin, uncorrected disturbances of the electrolyte and fluid balances (such as hypotonic dehydration, hypokalaemia, hyperhydration), intrahepatic cholestasis.

Special warnings and precautions for use

Hypersensitivity reactions to one of the ingredients of Lipofundin® MCT/LCT 10%, (e.g. traces of protein in soya oil or egg lecithin), are extremely rare, however, these cannot be totally excluded for sensitised patients. Therefore particular caution should be observed when Lipofundin® MCT/LCT 10% (or fat emulsions in general) are to be administered to such patients.

If fat is to be administered in high doses every day there should be controls of serum triglycerides and, if necessary, of blood sugar, acid base and electrolyte status after the first day of infusion and then at suitable intervals.

The water balance and/or body weight should be monitored daily. Because alterations in the blood cell counts may be symptoms of overdose, monitoring of the blood cell counts is advisable.

In the case of patients suspected to have disturbances of lipid metabolism fasting hyperlipaemia should be excluded by determination of the serum triglyceride concentration. If during infusion the serum triglyceride concentrations exceed 3 mmol/l in adults and 1.7 mmol/l in children the infusion rate must be reduced or the infusion must be stopped. Serum triglyceride concentrations exceeding above values 12 hours after the lipid infusion has been stopped also indicates disturbance of lipid metabolism. Fat administration should also be interrupted if there is a marked increase of the blood glucose concentration during fat infusion.

Using fat emulsions as the only calorie source may provoke metabolic acidosis. Simultaneous carbohydrate infusions will prevent those complications. Therefore, fat infusions should always be accompanied by infusions of sufficient amounts of carbohydrate containing solutions.

Vitamin E may have an influence on the effect of vitamin K in the synthesis of coagulation factors. Therefore, in patients receiving oral anticoagulants and suspected to have vitamin K deficiency, monitoring of the coagulation status is recommended.

Pregnancy and lactation

The safety of Lipofundin® MCT/LCT 10% during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard. Nevertheless, medicines should not be used in pregnancy, especially during the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

Interactions

Interactions with other medicaments are not known so far.

Lipofundin® MCT/LCT 10% must not be used as vehicle solutions for electrolyte concentrates or other medicaments. Uncontrolled mixing with other infusion solutions should also be avoided because adequate stability of the emulsion would no longer be guaranteed.

Combined regimes are only to be used for parenteral nutrition after their pharmaceutical compatibility has been controlled and guaranteed.

Admixture of alcohol containing injections or infusion solutions must be strictly avoided.

Dosage

As a rule, depending on calorie requirements

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1. Adults and school-age children
1 - 2 g fat per kg body weight per day, corresponding to
10 - 20 ml Lipofundin® MCT/LCT 10% per kg body weight per day

2. Neonates
2 - 3 (max. 4) g lipid per kg body weight per day, corresponding to
20 - 30 (up to 40) ml Lipofundin® MCT/LCT 10% per kg body weight per day.
The ability to eliminate triglycerides and lipids is not fully developed, particularly in the case of premature and hypotrophic neonates, hence to dosage limits should not be exploited completely and triglyceride and fatty acids should be monitored very carefully. There must not be any hyperlipaemia at the end of the interval between the daily infusions.

3. Infants and pre-school children
1 - 3 g lipid per kg body weight per day, corresponding to
10 - 30 ml Lipofundin® MCT/LCT 10% per kg body weight per day.

Infusion rate
The infusion rate should be as low as possible. The infusion rate during the first 15 minutes of the infusion should not exceed
0.05 – 0.1 g lipid per kg body weight per hour, corresponding to
0.5 – 1.0 ml of emulsion per kg body weight per hour.

Maximum infusion rate:
Up to 0.15 g lipid per kg body weight per hour, corresponding to up to 1.5 ml Lipofundin® MCT/LCT 10% per kg body weight per hour.
Accordingly, the drop rate should not exceed 0.5 drops per kg body weight per minute.
This means that for a patient weighing 70 kg the maximum infusion rate may be approx. 100 ml/hour or 35 drops/min.
The infusion rate should be reduced in malnourished patients and in children.
It is recommended that the infusion rate be so chosen that the planned daily dose can be administered within 24 hours or not less than 16 hours per day.

Duration of use
The duration of administration of the fat emulsion as part of a complete parenteral nutrition is generally 1 - 2 weeks. If parenteral nutrition with lipid emulsions is further indicated, the emulsion can be administered over longer periods provided appropriate monitoring is employed.

Method of administration
As intravenous infusion
Lipid emulsions are suitable for peripheral venous administration and can also be administered separately via peripheral veins as part of total parenteral nutrition.
If infusion sets with in-line filters are used they must be lipid-permeable.
When lipid emulsions are to be simultaneously infused with amino acid and carbohydrate solutions the Y- or the bypass connector should be placed as close to the patient as possible. It should be made sure that solutions to be infused together with Lipofundin MCT/LCT 10% through the same tubing are compatible with the fat emulsion.
When administering the fat emulsion from flexible bags, the air vent of the infusion set must be closed.
Only infuse emulsions having room temperature!

Overdose

Symptoms
Overdose can cause an overload syndrome showing the following symptoms: fever, headache, abdominal pain, fatigue, hyperlipaemia, hepatomegaly with or without jaundice, splenomegaly, pathological liver function tests, anaemia, reduction of platelet counts, reduction of leucocyte counts, haemorrhage and tendency to haemorrhage, alterations or reductions in blood coagulation factors (as indicated by pathological values of bleeding time, coagulation time, prothrombin time etc.).

Emergency treatment, antidotes
Immediate cessation of infusion. Further therapy is determined according to the individual symptoms and their severity; in some circumstances it may be necessary to transfuse blood or blood components.

Undesirable effects
In very rare cases there can be acute reactions such as dyspnoea, cyanosis, allergic reactions, hyperlipaemia, marked hyperglycaemia, hypercoagulability, nausea, vomiting, headache, flush, hyperthermia, hypertension or hypotension, sweating, shivering, drowsiness, chest and back pain during the intravenous infusion of lipids. The infusion should be stopped in such cases. When the symptoms have disappeared and elevated serum triglyceride concentrations (or lipaemic serum turbidity) have normalised it is generally possible to recommence the infusion at a lower flow rate and/or dose. In such cases the patients should be carefully monitored, particularly in the initial stages, and the serum triglyceride concentrations (serum turbidity) should be controlled at short intervals.
In the case of patients suspected to have disturbances of lipid metabolism fasting hyperlipaemia (serum triglyceride concentrations above 3 mmol/l in adults and above 1.7 mmol/l in children) should be excluded before the commencement of infusion. In the presence of fasting lipaemia, the further administration of lipid emulsions is contraindicated.
Hyperlipaemia (serum triglyceride concentrations above 3 mmol/l in adults and above 1.7 mmol/l in children) 12 hours after the lipid infusion has been stopped also indicates disturbance of lipid metabolism.

Note:
Patients are advised to inform their doctor or pharmacist if they notice any adverse effect not mentioned in this leaflet.

Expiry date
The product must not be used beyond the expiry date stated on the labelling.

Storage
Do not store above 25 °C

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