



381/12260986/0113

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Description

LIPOFUNDIN® MCT/LCT is a sterile, non-pyrogenic fat emulsion for intravenous administration.

Composition

Each 1000 ml contains

| | 20 % |
|-------------------------------------------------------------------|-------------------------|
| Soya –bean Oil | 100.0 g |
| Medium-Chain Triglycerides (MCT) | 100.0 g |
| Egg Yolk Phospholipids (Egg lecithin) | 12.0 g |
| Glycerol | 25.0 g |
| Sodium Oleate (C ₁₈ H ₃₃ NaO ₂) | 0.3 g |
| α-tocopherol | 0.2 g |
| Water for injection | to 1000 ml |
| Caloric Value | 7990 kJ/kl= 1908 kcal/l |
| Osmolarity | 380 mOsm/l |

Soybean oil is a refined natural product containing neutral triglycerides of predominantly unsaturated fatty acids.

Medium chain triglycerides are a mixture of neutral triglycerides of mainly caprylic (about 60%) and capric acid (about 40%).

Clinical Pharmacology

The mode of action is just the same as the one given orally. Medium chain triglyceride as a source of calories. Long chain triglyceride supplies essential fatty acid which needed by the body.

Indications

LIPOFUNDIN® MCT/LCT is indicated as a sources of calories and essential fatty acids for patient requiring parenteral nutrition.

Contraindications

The administration of LIPOFUNDIN® MCT/LCT is contraindicated in patients demonstrating disturbances in normal fat metabolism such as pathologic hyperlipemia. Lipoid nephrosis or acute pancreatitis if accompanied by hyperlipemia. It is further contraindicated in patients with ketoacidosis or hypoxia, in thrombo-embolism and in acute shock states. Since egg yolk phospholipides are present do not administer to patients with severe egg allergies.

Warnings

Caution should be exercised in administering intravenous fat emulsion in patients with metabolic acidosis, severe liver damage pulmonary disease, sepsis, disease of the reticuloendothelial system, anemia or blood coagulation disorders, or when there is danger of fat embolism.

The too rapid infusion of fat emulsion can cause fluid and/or fat overloading resulting in dilution of serum electrolyte concentrations, overhydration, congestes states, pulmonary oedema, impaired pulmonary diffusion capacity.

Lipofundin® MCT/LCT 20% Lipids Emulsion for infusion

A too rapid infusion of LIPOFUNDIN® MCT/LCT can also cause hyperkeonaemia and/or metabolic acidosis, especially when carbohydrates are not administered simultaneously.

Precautions

The administration of LIPOFUNDIN® MCT/LCT should be accompanied by simultaneous carbohydrates infusions making up to 40% (at least) of the total calorie intake.

When LIPOFUNDIN® MCT/LCT in administered, the patient's capacity to eliminate the infused fat from the circulation must be monitored. The Lipaemia must be clear between daily infusions.

Especially where fat emulsion are administered fat extended period of time, the patient's haemogram, blood coagulation, liver function, and platelet count should be closely monitored.

Children : no data are available on the use of LIPOFUNDIN® MCT/LCT in children.

Elderly : Experience of the use of LIPOFUNDIN® MCT/LCT in the elderly is limited, although there is no evidence to suggest the dosage should be different from that recommended for other adult patients. Nevertheless metabolic rates and patterns can vary in the elderly, so careful monitoring of this particular group of patients is always prudent.

Use in pregnancy : The safety of LIPOFUNDIN® MCT/LCT during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard, nevertheless medicine 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.

Adverse Reactions

Adverse reaction directly related to fat emulsions in general are of two types :

1. Immediate (acute) reactions : dyspnea, cyanosis, allergic reactions, hyperlipaemia, hypercoagulability, nausea, vomiting, headache, flushing, hyperthermia, sweating, chills, sleepiness, chest and back pain.

2. Delayed reaction : hepatomegaly, jaundice due to centrallobular cholestasis, splenomegaly, thrombocytopenia, leucopenia, transient increases in liver function test, and overloading syndrome. The deposition of a brown pigmentation in the reticuloendothelial system, the so called "intravenous fat pigment", has also been reported. The cause and the significance of this phenomenon are unknown.

Dosage

Adult patients

LIPOFUNDIN® MCT/LCT can provide up to 60% of the daily non-protein calories at an average dose of 1-2 g/kg of body weight per day.

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LIPOFUNDIN® MCT/LCT 20%

The infusion rate (for 70 kg patient) for the first 15 minutes should not be exceed 0,25-0,5 ml/kg body/weight/hour. If no adverse effects are observed during this initial infusion, the rate can be increased to 1 ml/kg body weight/hour.

Not more than 250 ml of LIPOFUNDIN MCT/LCT 20% should be infused into adults on the first day of the therapy. If the patients show no untoward reaction, the dose can be increased on the following day. Maximum therapy should not more than 10 days.

Fat emulsion should be allowed to warm to room temperature before infusion.

Overdosage

In the event of fat overloaded during therapy, stop the infusion of LIPOFUNDIN® MCT/LCT, until visual inspection of the plasma, determination of trygliceride concentrations, or measurement of plasma light scattering activity by nephelometry indicate the lipid has cleared. Reevaluated the patient and institute appropriate corrective measures. See WARNING and PRECAUTIONS.

Administration

LIPOFUNDIN® MCT/LCT should be administered as apart of a total parenteral nutrition regimen via peripheral vein or central venous catheter. LIPOFUNDIN MCT/LCT can be infused into the same central or peripheral vein as the carbohydrate/amino acid solutions by means of a short Y-connector near the infusion site. This allows for mixing of the solutions immediately before entering the vein. Flow rates of each solution should be controlled separately by infusion pumps, if there are used.

As a general rule fat emulsion should not be mixed with electrolyte, drugs or any other additives in infusion bottle.

LIPOFUNDIN® MCT/LCT may be used with nutrient mixing bag systems only if such resultant mixtures are compatible and stable.

Notice

LIPOFUNDIN® MCT/LCT is supplied in single dose containers. Unused contents must be discarded and should not be stored for later use.

Filters should not be used with fat emulsion.

Do not use any bottle in which there appears to be a separation (oiling out) of the emulsion

Expiry date

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

Storage

Do not store above 25°C

Presentation

Lipofundin® MCT/LCT 20%, 100 ml, 250 ml and 500 ml glass bottle No. Reg. DKI 1186701249 A1

Harus dengan resep dokter

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PT. B. Braun Medical Indonesia
Jakarta-Indonesia

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Manufactured by:
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34209 Melsungen
Germany

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