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Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Lipofundin MCT/LCT 10% and 20%

Composition

1000 ml emulsion contain	Lipofundin MCT/LCT 10%	Lipofundin MCT/LCT 20%
Soya Oil	50.0 g	100.0 g
Medium-chain Triglycerides	50.0 g	100.0 g
Glycerol	25.0 g	25.0 g
Egg Lecithin	8.0 g	12.0 g
α-Tocopherol	0.1	0.2
Sodium Oleate, Water for Injections		
Megajoules/l (approx)	4.28 (1022 Kcal)	7.99 (1908 Kcal)
Milliosmols/l (approx)	345	380
pH:	6.5 - 8.8	6.5 - 8.5

Pharmaceutical form
Emulsion for intravenous infusion in glass bottles, contents:
100 ml, 250 ml, 500 ml

Pharmaco-therapeutic group
Fat emulsion for provision of calories and essential fatty acids.

Indications
Lipofundin MCT/LCT is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition.

Contraindications
The administration of Lipofundin MCT/LCT is contra-indicated in patients demonstrating disturbances in normal fat metabolism such as pathologic hyperlipaemia, lipoid nephrosis, severe liver damage or acute pancreatitis if accompanied by hyperlipaemia. It is further contraindicated in patients with ketoacidosis or hypoxia, in thromboembolism and in acute shock states.

Monitoring
Electrolyte, fluid, acid-base imbalance and shock should be corrected prior to commencement of intravenous nutrition. In the metabolic and nutritional management of the seriously ill patient, specific preliminary investigations and continuous monitoring are essential, particularly of electrolyte levels. Monitoring of vitamin and trace element levels should be included, especially in patients receiving long-term intravenous nutrition.

Precautions for use
Caution should be exercised in administering intravenous fat emulsions in patients with metabolic acidosis, liver damage, pulmonary disease, sepsis, diseases of the reticuloendothelial system, renal insufficiency, uncompensated diabetes mellitus, hypothyroidism (if hypertriglyceridemic) anemia or blood coagulation disorders or when there is danger of fat embolism.
Administration of Lipofundin MCT/LCT should be accompanied by simultaneous carbohydrate infusions making up to 40% (at least) of the total calorie intake. When Lipofundin MCT/LCT is administered, the patient's capacity to eliminate the infused fat from the circulation must be monitored.
In patients with the above mentioned disorders, the elimination of fat should be checked daily. The lipaemia must clear between daily infusion.
Monitoring of fat elimination is done by collecting a blood sample after a fat free clearance period of 4-6 hours. Blood cells are then separated from plasma by centrifugation (1200-1500 rotations per minute, rpm). If the plasma is opalescent, the infusion should be postponed. The sensitivity of the method is such that hypertriglyceridaemia can pass undetected. Therefore, it is recommended that serum triglyceride concentrations are measured in patients who are likely to have an impaired fat
tolerance.
Especially where fat emulsions are administered for extended of time and in neonates, the patient's haemogram, blood coagulation, liver function and platelet count should be closely
monitored.
Patients known to be allergic to soy protein, should be given Lipofundin MCT/LCT with caution and only after hypersensitivity tests. In newborns with neonatal hyperbilirubinaemia, Lipofundin MCT/LCT should be used with caution, especially in low birth-weight infants, because of the risk of free fatty acids displacing bilirubin from albumin. To premature and low birth-weight infants, Lipofundin MCT/LCT should be administered continuously during 24 hours/day.

Use in pregnancy and lactation
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, 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
Lipofundin MCT/LCT may interfere with certain laboratory measurements (bilirubin, lactate dehydrogenase, oxygen saturation, Hb etc) if blood is sampled before fat is adequately cleared from the blood stream. Fat is cleared after a fat-free interval of 4 to 6 hours in most patients.
Some drugs, like insulin, may interfere with body's lipase system. However, this kind of interaction seems to be of only limited clinical importance.
Heparin in clinical doses, causes a transient increase in lipolysis in plasma, resulting in a transient decrease in triglyceride due to depletion of lipoprotein lipase.
Soybean oil has a natural content of vitamin K. This is considered important only for patients treated with coumarin derivatives which interfere with vitamin K.
As a general rule, fat emuisions should not be mixed with electrolytes, drugs or any other additives in the infusion bottle. Lipofundin MCT/LCT may be used with nutrient mixing bag systems only if such resultant mixtures are compatible and stable.

Special warnings
The too rapid infusion of fat emulsions can cause fluid and/or fat overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, pulmonary oedema, impaired pulmonary diffusion capacity, fat embolism.
A too rapid infusion of Lipofundin MCT/LCT can also cause hyperketonaemia and/or metabolic acidosis, especially when carbohydrates are not administered simultaneously.

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Dosage

The dosage and infusion rate should be within the ranges recommended below and should be governed by the patient's ability to utilise fat.

1. Adults and school-age children

1-2 g fat per kg body weight per day, corresponding to 10-20 ml of Lipofundin MCT/LCT 10% or 5-10 ml of Lipofundin MCT/LCT 20% per kg body weight per day.

2. Neonates, infants and pre-school children.

Dosage is governed by the maturity and birth-weight of the infant.

Neonates

2.5-3 g (up to 4 g) of fat per kg body weight per day, corresponding to 25-30 ml (up to 40 ml) of Lipofundin MCT/LCT 10% or 12.5-15 ml (up to 20 ml) of Lipofundin MCT/LCT 20% per kg body weight per day.

Especially in preterm infants and low-birth-weight neonates, the ability to eliminate infused lipids is not yet fully developed. Therefore maximum fat doses should not be administered to these patients. The infant's ability to eliminate infused fat from the circulation should be checked daily. Measuring serum triglycerides is the only reliable method. If lipaemia is present retesting should be carried out after an interval of four hours.

At the end of the daily fat-free interval, the fat must have been cleared from the serum.

Infants and pre-school children

0.5-3 g of fat per kg body weight per day, corresponding to 5-30 ml of Lipofundin MCT/LCT 10% or 2.5-15 ml of Lipofundin MCT/LCT 20% per kg body weight per day.

3. Elderly

Age per se requires no adjustment of the adult dosage. However, caution should be exercised in the "frail" and indeed in all patients with poor renal, cardiac or liver function, where smaller volumes should be used depending on the individual's requirements and condition.

Infusion rates

In general, fat emulsions should be infused at as low a rate as possible. During the first 15 minutes the infusion rate should not exceed 0.05-0.1 g of fat per kg body weight and hour, corresponding to 0.5-1.0 ml of Lipofundin MCT/LCT 10% or 0.25-0.5 ml of Lipofundin MCT/LCT 20% per kg body weight and hour. If no adverse reactions are observed during this initial phase, the infusion rate may be increased to 0.15-0.2 g fat per kg body weight per hour, corresponding to 1.5-2.0 ml of Lipofundin MCT/LCT 10% or 0.75-1.0 ml of Lipofundin MCT/LCT 20% per kg body weight and hour. The daily fat infusions should be administered over not less than 16 hours, preferably as continuous infusion over 24 hours.

To premature and low birth-weight infants Lipofundin MCT/LCT should be administered continuously during 24 hours/day. The dose can only be increased up to a maximum of 4.0 g/kg/24 hours by concomittant careful monitoring by following the triglyceride levels, liver function tests and oxygen saturation. The rates given are maximum rates and no attempt should be made to exceed these in order to compensate for missed doses.

Duration of use

In total parenteral nutrition, Lipofundin MCT/LCT is normally administered over 1-2 weeks. If fat infusions are further indicated and appropriate monitoring is instituted, the period of use of Lipofundin MCT/LCT may be extended.

Method and route of administration

Lipofundin MCT/LCT should be administered by intravenous infusion as part of a total parenteral nutrition regimen via a peripheral vein or central venous catheter. Lipofundin MCT/LCT can be infused into the same central or peripheral vein as the carbohydrate and 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 for each solution should be controlled separately by infusion pumps, if these are used.

For safe administration of intravenous fluids from non-collapsible containers a giving set with a integral airway is recommended.

Infusion sets with in-line filters are not to be used for administration of fat emulsions.

Overdosage

Overdosage lending to fat overload syndrome may occur, acutely as a result of too rapid an infusion rate, or chronically at recommended rates of infusion in association with a change in the patient's clinical condition, e.g. renal function impairment or infection. Fat overload syndrome is characterised by hyperlipidaemia, fever, fat infiltration, organ dysfunction and coma. All symptoms are usually reversible if the infusion is discontinued.

In the event of fat overload during therapy, stop the infusion of Lipofundin MCT/LCT, until visual inspection of the plasma, determination of triglyceride concentrations, or measurement of plasma light-scattering activity by nephelometry indicate the lipid has cleared. Re-evaluate the patient and institute appropriate corrective measures.

Undesirable effects

Adverse reactions 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 reactions: hepatomegaly, jaundice due to central lobular cholestasis, splenomegaly, thrombocytopenia, leucopenia, transient increases in liver function tests, and overloading syndrome. The deposition of a brown pigmentation in the reticuloendothelial system, the so-called "intravenous fat pigment", has been reported. The cause and the significance of this phenomenon are unknown.

Expiry date

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

Storage

Store below 25 °C., Protect from freezing. If accidentally frozen, discard bottle.

Unused contents must be discarded and should not be stored for later use.

Do not use bottles showing evidence of phase separation.

Presentation

100 ml, 250 ml and 500 ml glass bottle

Manufacturer:

B. Braun Melsungen AG
34209 Melsungen
Germany

License Holder

Lapidot Medical Import and Marketing Ltd.
8 Hashita st. Caesarea Industrial Zone 38900

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