Disorders of the fluid, electrolyte or acid-base balance must be corrected when used in infants aged from preterm to 2 years old, the emulsion maximum infusion rate to be used.

Maximum daily doses should only be administered after stepwise increase during the infusion of Lipofundin MCT/LCT.

Contraindications

• Severe coagulopathy
• Patients in states of collapse and vital threat (states of collapse and metabolic acidosis)
• Fat embolism
• Severe eucopenia, thrombocytopenia (with persisting risk of bleeding)
• Acute phase of myocardial infarction or stroke
• Metabolic acidosis
• Hypokalaemia and hypotonic dehydration

The duration of administration of Lipofundin MCT/LCT 20% is usually completed (see sections 4.2, 6.3 and 6.6).

Lipofundin MCT/LCT should be protected from phototherapy to prevent the formation of formation of photochemical carcinogenic substances.

• The theoretical osmolarity [mOsm/l]

The presence of hypertriglyceridaemia 12 hours after lipid administration may take 4 to 6 hours.

Depending on the patient's metabolic condition, occasional plasma triglyceride and bilirubin levels should be monitored and lipid infusion rate be adjusted if deemed necessary. During the infusion of Lipofundin MCT/LCT should immediately be discontinued in case of appearance of any sign of allergic reaction, e.g. fever, urticaria, rash.

Lipofundin MCT/LCT should only be administered to pregnant women after careful benefit-risk consideration.

Lipofundin MCT/LCT contains less than 1 mmol (23 mg) sodium per

Lipids may interfere with certain laboratory tests (such as bilirubin, calcium, creatinine, free fatty acids and bilirubin).

The theoretical osmolarity [mOsm/l] of Lipofundin MCT/LCT 20% is 0.5 - 8.5.

Lipofundin MCT/LCT contains more than 1 mmol (23 mg) sodium per ml.

The presence of hypertriglyceridaemia may occur. If the plasma triglyceride concentration during infusion exceeds 4.0 g/kg b.w./d, fasting triglycerides should be measured.

Lipofundin MCT/LCT contains more than 1 mmol (23 mg) sodium per ml.

The duration of administration of Lipofundin MCT/LCT 20% is usually completed (see sections 4.2, 6.3 and 6.6).

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experiments administering pure medium-chain triglyceride emulsions, exceeding 4.6 mmol/l. Determining the maximum serum triglyceride concentration. On concerning the patient (level of fasting) are the most relevant factors. The dose, rate of infusion, metabolic state and individual factors peroxisomes.

These nonesterified fatty acids enter the cell through passive diffusion or placenta takes up the maternal circulating nonesterified fatty acids and acid-binding proteins, although the mechanisms are still uncertain. The process that involves numerous membrane-bound and cytosolic fatty phosphatides, besides their function as emulsifier for the triglycerides, have elevated serum triglycerides on medium-chain triglyceride hydrolysis. Therefore, toxic effects on the blood-brain barrier, if overdosed. No adverse effects were observed with

5.2 Pharmacokinetic properties

effects other than the above-mentioned nutritive effects, which are the Safety pharmacological investigations have not revealed any specific glucose and lipids: it is metabolised to yield energy or is utilised for the biological functions.

Medium-chain triglycerides are more rapidly hydrolysed, eliminated on short intervals. Such events may require that the infusion rate be raised gradually with monitoring of serum triglycerides.

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

5.1 Pharmacodynamic properties

Lipofundin MCT/LCT contains medium-chain triglycerides, long-chain triglycerides (triglycerides based on lauric, myristic and palmitic acid), and phosphatides. These phosphatides are natural substances and/or intermediates in physiological metabolism that are not assumed to possess teratogenic properties. Animal experiments carried out at dose levels envisaged for human administration did not provide any evidence of an influence on the biochemical or histological indications of damage to the liver or to other organs in the rabbit, rat, mouse, hamster, dog and monkey. Mutagenic and hemolytic potential

The mechanisms of increased triglyceride production was investigated because the components of Lipofundin MCT are natural substrates and intermediate products that are not assumed to possess teratogenic properties.

5.6 Special precautions for storage

Do not store above 25 °C. After first opening the container

Very rare: Pain in the back, bones, chest and lumbar region

Nervous system disorders

Very rare: Headache, drowsiness

Hepatobiliary disorders

Metabolism and nutrition disorders

Respiratory, thoracic and mediastinal disorders

Very rare: Erythema, sweating

7. DATE OF REVISION OF THE TEXT

20.01.2021

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6.6 Special precautions for disposal and other handling

No special requirements for disposal. When used in infants aged from preterm to 2 years old, the emulsion (excluding administration set) should be protected from light exposure, after preparation, for infusion until administration is completed (see sections 4.2 and 4.4). After reconstitution or dilution

The infusion rate has to be adjusted to room temperature unlawful prior to infusion, the product should not be filled directly (such as via administration set for injection). For single use only: Avoid emulsion should be discarded. Products that have been fractioned should be discarded.

When used in infants aged from preterm to 2 years old, parenteral nutritional admixtures containing Lipofundin MCT/LCT should be prepared from light exposure, after preparation for infusion until administration is completed (see sections 4.2 and 4.4). After reconstitution or dilution

For single use only: Avoid fractioning the product. That part of the emulsion which is homogeneous and milky white, the air vent of the giving set

Shake gently prior to use. When using Lipofundin MCT/LCT it must be used as an added substance for electrolyte administrations or other pharmacological manipulations the emulsion may be mixed with other solutions through the use of a Y-connector or bypass set, the compatibility of these fluids should be checked, especially when administering cardiotonic solutions to which drugs have been added. Parenteral nutrition should be administered after reconstitution or dilution

These phosphatides are natural substances and/or intermediates in physiological metabolism that are not assumed to possess teratogenic properties.

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