

Package leaflet: Information for the user

Lipofundin MCT/LCT 20%

Emulsion for Infusion

Soya-bean oil, medium-chain triglycerides

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Lipofundin MCT/LCT 20% is and what it is used for

Lipofundin MCT/LCT 20% is a milky white, sterile emulsion. Lipofundin MCT/LCT 20% is used to provide fat, including essential fatty acids to patients needing to be fed intravenously (through a small tube placed into a vein) because they are unable to eat food normally or the normal intake is not enough.

The oils contained in Lipofundin MCT/LCT 20% are foodstuffs and they act as sources of energy and provide an essential nutrient, the essential fatty acids.

2. What you need to know before you use Lipofundin MCT/LCT 20%

Do not use Lipofundin MCT/LCT 20%

- if you are allergic to egg or soya-bean protein, soya-bean or peanut products or to any of the ingredients of this medicine (listed in section 6).

Do not use Lipofundin MCT/LCT 20% if you suffer from any of the following:

- severe increase in blood fat levels (severe hyperlipidaemia) • when you have a condition where the blood does not clot properly (severe coagulopathy, aggravating haemorrhagic diatheses)
- severe liver failure (severe hepatic insufficiency)
- impaired bile flow (intrahepatic cholestasis)
- blocking of blood vessels by blood clots or fat (acute thrombo-embolic event, fat embolism)
- conditions where the blood is too acidic (metabolic acidosis)
- life-threatening blood circulation problems, such as those that can occur if you are in a state of collapse or shock

- if you have unstable metabolism, e.g. because of severe injury or surgical procedures (post-aggression syndrome), infections involving the whole body (severe sepsis) or coma of unknown origin

- acute phase of heart attack (myocardial infarction) or stroke
- severe kidney failure (severe renal insufficiency) without dialysis treatment
- untreated disturbances in fluid or salt (electrolyte) balance, for example low body water and salt content (hypotonic dehydration) or low potassium levels (hypokalaemia) in your blood
- severe heart failure (decompensated cardiac insufficiency)
- accumulation of fluid in the lungs (acute pulmonary oedema)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Lipofundin MCT/LCT 20%.

During infusion, the amount of fat (serum triglycerides) in your blood should be regularly monitored by your doctor. If your blood fat values rises too high, your doctor may reduce the infusion speed or stop the infusion.

Before you receive this medicine any existing disorders of your body's fluid and salt content as well as disturbances of your acid-base balance should be corrected by your doctor.

While you receive this solution, your doctor should check your levels of fluids, blood salts and the acid-base balance as well as your heart function. Your doctor may consider it necessary that you receive this solution over several weeks. In this case your liver function as well as your blood clotting function should be monitored and blood cell counts should be performed.

Allergic reactions to this medicine are extremely rare. If you show signs of an allergic reaction – such as fever, shivering, rash, or breathing problems – when you receive this medicine, the infusion should be stopped immediately by your doctor.

In addition to Lipofundin MCT/LCT 20% you may receive a carbohydrate solution and an amino acid solution to prevent metabolic conditions where your blood becomes acidic (metabolic acidosis).

To make your intravenous feeding complete, you may also receive carbohydrate solutions and amino acid solutions. The nursing staff may also take measures to ensure that your body's fluid, electrolyte, vitamin and trace element requirements are met.

During infusion this solution should be protected from the light of a phototherapy to decrease the formation of potentially harmful substances (triglyceride hydroperoxides).

Elderly patients

In some conditions your ability to use fat correctly may be impaired. Your doctor will keep in mind that some of these conditions are frequently associated with advanced age, e.g. impaired heart or kidney function.

Patients with impaired lipid metabolism

In some conditions your ability to use fat correctly may be impaired. Therefore, it is important that your doctor knows:

- if you have diabetes mellitus
- if you have an inflammation of the pancreas (pancreatitis)
- if you have impaired liver or kidney function (renal insufficiency, impaired hepatic function)
- if you have blood poisoning (sepsis)
- if you have a reduced activity of the thyroid gland (hypothyroidism)

If your ability to use fat correctly is impaired, your doctor should closely monitor your blood fat (serum triglyceride) levels.

Children

In infants at risk of jaundice the blood fat (serum triglyceride) and bilirubin levels should be monitored by your doctor. It may become necessary for your doctor to adjust the daily fat doses.

Other medicines and Lipofundin MCT/LCT 20%

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Lipofundin MCT/LCT 20% can interact with some other medicines. Tell your doctor if you are taking or receiving certain medicines to control your blood clotting, namely:

- heparin
- coumarin products, for example warfarin.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There are no adequate data from the use of Lipofundin MCT/LCT 20% in pregnant women. If you are pregnant you will receive this medicine only if the doctor considers it absolutely necessary for your recovery.

Breast-feeding is not recommended for mothers on parenteral nutrition.

Driving and using machines

Lipofundin MCT/LCT 20% is normally given to immobile patients in a controlled setting (a hospital or clinic). This will exclude driving and using machines.

Lipofundin MCT/LCT 20% contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per litre, i.e. it is essentially 'sodium-free'.

3. How to use Lipofundin MCT/LCT 20%

This medicine is administered by intravenous infusion (drip), that is, through a small tube directly into a vein.

The following doses are recommendations for guidance. Your doctor will decide how much of this medicine you need and for how long you will require treatment with this medicine.

Adults

The usual dose is 0.7 – 1.5 g lipids/kg body weight per day. A maximum dose of 2.0 g lipids/kg body weight/day, for instance when your energy requirements are high or your fat utilisation is increased (e.g. cancer patients), should not be exceeded by your doctor.

In the following patient groups the provision of intravenous lipids should not exceed 1.0 g/kg body weight/day:

- Patients on long-term home parenteral nutrition treatment (> 6 months)
- Patients with short bowel syndrome

For a patient weighing 70 kg a daily dose of 2.0 g/kg body weight/day corresponds to a maximum daily dose of 700 ml Lipofundin MCT/LCT 20%.

Paediatric population

A successive increase of the lipid dose in steps of 0.5 – 1.0 g/kg body weight/day may be beneficial. It can help the doctor to monitor the increase of the plasma triglyceride level and to prevent too high blood fat levels (hyperlipidaemia).

Infants (0-2 years of age)

It is recommended not to exceed a daily lipid dose of 3.0 (max. 4.0) g/kg body weight/day. In this age group the daily dose of lipids should be infused continuously over about 24 hours.

Children and adolescents (>2 years of age)

It is recommended not to exceed a daily lipid dose of 2.0 – 3.0 g/kg body weight/day.

Infusion rate

The infusion should be administered at the lowest possible infusion rate. During the first 15 minutes the infusion rate should only be 50% of the maximum infusion rate to be used. The doctor should monitor the patient closely for the occurrence of side effects.

Maximum infusion rate

Adults

Up to 0.15 g lipids/kg body weight/hour.

For a patient weighing 70 kg this corresponds to a maximum infusion rate of 52.5 ml per hour Lipofundin MCT/LCT 20%. The amount of lipids administered then is 10.5 g per hour.

Infants (0-2 years of age)

Up to 0.17 g lipids/kg body weight/hour.

Children and adolescents (>2 years of age)

Up to 0.13 g lipids/kg body weight/hour.

If you use more Lipofundin MCT/LCT 20% than you should

If you have received too much Lipofundin MCT/LCT 20%, you may get abnormally high blood fat levels (hyperlipidaemia), your blood may become too acidic (metabolic acidosis) or you may suffer from a so-called 'fat overload syndrome'. For symptoms of the fat overload syndrome please see section 4 "Possible side effects".

If you have received too much Lipofundin MCT/LCT 20%, the infusion will be stopped. The infusion will not be started again until you have recovered. It may be necessary for your doctor to adjust the daily fat doses. Your doctor will decide on any additional treatment.

4. Possible side effects

Like all medicines, Lipofundin MCT/LCT 20% can cause side effects, although not everybody gets them.

The following side effects may be serious. If any of the following side effects occur, tell your doctor immediately, he will stop giving you this medicine:

Very rare (may affect up to 1 in 10,000 people)

- allergic reactions, for example skin reactions, shortness of breath, swelling of the lips, mouth and throat, difficulty breathing
- breathing problems (dyspnoea)
- bluish skin (cyanosis)

Other side effects:

Very rare (may affect up to 1 in 10,000 people)

- fat overload syndrome (see “Fat overload syndrome” below)
- increased tendency of your blood to clot (hypercoagulability)
- abnormally high blood fat levels (hyperlipidaemia)
- abnormally high blood sugar levels (hyperglycaemia)
- metabolic conditions where your blood becomes acidic (metabolic acidosis, ketoacidosis)
- decrease or increase in blood pressure
- drowsiness
- feeling sick, vomiting, loss of appetite
- headache
- flush
- reddening of the skin (erythema)
- high body temperature
- sweating
- feeling cold, chills
- pain in the back, bones, chest and lumbar region

Not known (frequency cannot be estimated from the available data)

- impaired bile flow (cholestasis)
- reduction of white blood cell count (leukopenia)
- reduction of blood platelet count (thrombocytopenia)

Fat overload syndrome:

You might suffer from a “fat overload syndrome” if you have received too much Lipofundin MCT/LCT 20% or when your body has problems using fat. Your body’s ability to use fat might be influenced by a sudden change in your condition (due to renal problems or an infection). The symptoms are usually reversible if the infusion is stopped. A fat overload syndrome is characterised by the following symptoms:

- high blood fat levels (hyperlipidaemia)
- fever
- deposition of fat in the liver or other organs (fat infiltration)
- enlargement of the liver (hepatomegaly), which may sometimes be accompanied by jaundice (icterus)
- enlargement of the spleen (splenomegaly)
- reduction of red blood cell count (anaemia)
- reduction of white blood cell count (leukopenia)
- reduction of blood platelet count (thrombocytopenia)
- disorder of blood clotting
- rupture of blood cells (haemolysis)
- increase in immature red blood cells (reticulocytosis)
- abnormal liver function tests
- loss of consciousness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lipofundin MCT/LCT 20%

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date that is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store bottles in the outer carton, in order to protect from light.

Do not freeze. Emulsions that have been frozen must be discarded.

Do not use if Lipofundin MCT/LCT 20% if you notice:

- large oil drops in the emulsion or two separate layers of fluid
- discoloration
- damage of the container or the closure

6. Contents of the pack and other information

What Lipofundin MCT/LCT 20% contains

Lipofundin MCT/LCT 20% is an emulsion of oils in water. It contains 20 percent (weight per volume) of a mixture of oils.

- The active substances in 1 000 ml Lipofundin MCT/LCT 20 % are:

Medium-chain triglycerides	100.0 g
Soya-bean oil, refined	100.0 g

Energy	8095 kJ/l \cong 1935 kcal/l
Osmolarity	380 mOsm/l
Acidity or alkalinity (titration to pH 7.4)	< 0.5 mmol/l
pH	6.0 – 8.5

- The other ingredients are:

glycerol,
egg phospholipids for injection,
all rac α -tocopherol,
sodium oleate
water for injections.

What Lipofundin MCT/LCT 20% looks like and contents of the pack

Lipofundin MCT/LCT 20 % is a milky white, sterile emulsion for infusion (i.e., for administration directly into a vein.), contained in glass bottles of 100 ml, 250 ml or 500 ml size.

It is available in packs of:

10 x 100 ml, 10 x 250 ml, 10 x 500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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Carl-Braun-Straße 1,
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The following information is intended for healthcare professionals only:

Additional special warnings and precautions for use

Mixing with incompatible substances might lead to breaking of the emulsion or to precipitation of particles, both resulting in a high risk of embolism.

In solutions with higher lipid concentration (e.g. Lipofundin MCT/LCT 20%), the ratio of emulsifier (phospholipid) to oil is lower than in lower concentrated lipid emulsions. This ensures a favourable lower plasma concentration of triglycerides, phospholipids, free fatty acids as well as the pathological lipoprotein X in the patient`s blood. Therefore higher concentrated lipid emulsions like Lipofundin MCT/LCT 20% should be preferred over lower concentrated lipid emulsions.

Interference with laboratory tests

Lipids may interfere with certain laboratory tests (such as bilirubin, lactate dehydrogenase, oxygen saturation) when the blood sample is taken before the lipids have been eliminated from the bloodstream; this may take 4 to 6 hours.

Incompatibilities

Lipofundin MCT/LCT 20% must not be used as carrier solution for electrolyte concentrates or other pharmaceuticals nor must the emulsion be mixed with other infusion solutions, since adequate stability of the emulsion would no longer be guaranteed.

Special precautions for disposal and other handling

Shake gently prior to use.

The emulsion has to be brought to room temperature unaided prior to infusion, i.e., the product should not be put in a heating device (such as oven or microwave).

If filters are used they must be permeable to lipids.

Before infusing a lipid emulsion together with other solutions via a Y connector or bypass set, the compatibility of these fluids should be checked, especially when co-administering carrier solutions to which medicinal products have been added. Particular caution should be exercised when co-infusing solutions that contain divalent electrolytes (such as calcium or magnesium).

Method of administration

Lipid emulsions are suitable for peripheral venous administration and can also be administered separately via peripheral veins as part of total parenteral nutrition.

The Y- or the bypass connector should be placed as close to the patient as possible, if lipid emulsions are co-administered with amino acid and carbohydrate solutions.

The duration of administration of Lipofundin MCT/LCT 20% is usually 1 - 2 weeks. If parenteral nutrition with lipid emulsions is further indicated, Lipofundin MCT/LCT 20% can be administered over longer periods provided appropriate monitoring is employed.