



PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Melsungen AG · 34209 Melsungen, Germany

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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Lipofundin MCT/LCT 20 % is and what it is used for
2. Before you use Lipofundin MCT/LCT 20 %
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1. WHAT LIPOFUNDIN MCT/LCT 20 % IS AND WHAT IT IS USED FOR
Lipofundin is a milky white, sterile emulsion. Lipofundin 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 are foodstuffs and they act as sources of energy and provide an essential nutrient, the essential fatty acids.

2. BEFORE YOU USE LIPOFUNDIN MCT/LCT 20 %

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

- an **allergy (hypersensitivity) to eggs or soya-bean protein** or to **any of the ingredients of the emulsion**.
- severe hyperlipidemia (**high levels of fat substances in the blood**)
- severe blood coagulation disorders (conditions where the **blood does not clot properly**)
- intrahepatic cholestasis (a condition where the **flow of bile is impaired**)
- **severe liver failure**
- **severe kidney failure** and are not receiving dialysis treatment.
- acute heart infarction (**heart attack**) or **stroke**
- **acute blockage of blood vessels by blood clots or fat drops** (acute thrombo-embolism, fat embolism)
- **Severely impaired blood circulation, accompanied by massive impairment of heart function, breathing, kidney and liver function**, i.e. states of collapse or shock
- **Unstable metabolism because of severe injury, diabetes mellitus, severe sepsis (infection involving the whole body) and acidosis (where the blood is too acidic)**
- Unconsciousness (**coma**) caused by a special metabolic abnormality called **keto-acidosis**
- **Coma of unknown origin**
- Hypotonic dehydration (**too little water and too little salt in the body**)
- Hypokalaemia (**abnormally low potassium levels in the blood**)

Patients must not receive infusion therapy if one or more of the following conditions are present:

- Acute pulmonary oedema (**accumulation of fluid in the lungs**)
- Hyperhydration (**too much water in the body**)
- Decompensated cardiac insufficiency (**heart failure**)

Take special care with Lipofundin MCT/LCT 20 %:

Before this product is given to you, your doctor will check whether or not you have one or more of the following conditions, in which the body may not be able to use fat correctly:

- **diabetes mellitus**
- **inflammation of the pancreas** (pancreatitis)
- **impaired liver or kidney function**
- **lung disease**
- **sepsis (infection involving the whole body)**
- **underactive thyroid gland** (hypothyroidism)

If you have any of these conditions, Lipofundin MCT/LCT 20 % will only be administered if clearly needed and special care will be taken to make sure this product will not be harmful to you.

Because of the risk of allergic reactions, you should be monitored closely during beginning of the infusion. **If there is any sign of allergic reaction, e. g. fever, shivering, rash or dyspnoea (shortness of breath), the infusion should be discontinued.**

Taking other medicines:

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

Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine. The safety of use of Lipofundin MCT/LCT 20 % during pregnancy and lactation has not definitely been established. You will receive this medicine only if the doctor considers it absolutely necessary to save your life or to prevent any serious injury from occurring. Consideration should be given to stopping breast-feeding temporarily while under treatment with Lipofundin MCT/LCT 20 %.

Driving and using machines:

The conditions for which Lipofundin MCT/LCT 20 % is intended for use will normally exclude driving and using machines.

3 HOW TO USE LIPOFUNDIN MCT/LCT 20 %

This medicine will be administered to you by a doctor or healthcare professional

It will be given by an intravenous drip as part of a feeding programme. The amount (dose) and the drop (or infusion) rate of the fat emulsion will be decided by your doctor. The daily doses will be adjusted to your needs and body weight.

Lipofundin infusions will not be given alone but always together with sufficient amounts of amino acids and carbohydrate (normally glucose) infusions.

Lipofundin MCT/LCT 20 % will normally be given over a period of 1 week. Lipofundin MCT/LCT 20 % may be given for a longer period time if thought necessary by your doctor. Under these circumstances, you will be carefully monitored.

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

Overdose or too high infusion rate may lead to the so-called fat overload syndrome. This may show the following signs or symptoms: high levels of fat in the blood, fever, deposition of fat in the liver or other organs,

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swelling of the liver, which may sometimes be accompanied by jaundice, swelling of the spleen, low levels of red blood cells, white blood cells and platelets, disorder of blood clotting, destruction of red blood cells, other abnormalities of blood cells, abnormal liver function tests and loss of consciousness.

Marked overdose of fat emulsions may also lead to acidosis (where your blood becomes acidic).

If such undesirable effects occur during therapy, the infusion of Lipofundin MCT/LCT 20 % will be stopped. The infusion will not be started again until the fat has cleared from the blood and you have recovered. It may be necessary to make changes to the daily fat doses. Your doctor will decide on any additional treatment to be given.

4. POSSIBLE SIDE EFFECTS

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

Undesirable effects occur only very rarely (in less than one of 10 000 treated patients), provided that the instructions for using this product are followed correctly. The following undesirable effects may occur during or after the administration of fat emulsions (side effects are listed according to affected organs or organ systems):

Blood, lymphatic system

Increased tendency of the blood to clot

Immune system

Allergic reactions. Symptoms may include: fever, shivering, rash or dyspnoea (shortness of breath),

Metabolism

High blood fat and blood sugar levels, acidosis

As a result of an impaired capacity to use infused fat, the **fat overload syndrome** may develop. The signs and symptoms are described above under **"If you use more Lipofundin MCT/LCT 20 % than you should"**

As soon as a fat overload syndrome appears the fat infusion must be stopped.

Nervous system

Drowsiness

Circulation

Drop or raise of blood pressure

Lungs, airways

Breathing problems, cyanosis (bluish discoloration of the skin)

Stomach, gut

Feeling sick, vomiting

General disorders

Headache, flushing, fever, sweating, chills, chest and back pain.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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.

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 Lipofundin MCT/LCT 20 % out of the reach and sight of children.

Do not store above 25°C.

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

Do not freeze.

Do not use Lipofundin MCT/LCT 20 % after the expiry date which is stated on the label and the outer carton.

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

- large oil drops in the emulsion or two separate layers of fluid

- discoloration

- damage of the container or the closure

6. FURTHER INFORMATION

What Lipofundin MCT/LCT 20 % contains

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

• The active substances in 1000 ml Lipofundin MCT/LCT 20 % are:

Medium-chain triglycerides 100.0 g

Soya-bean oil, refined 100.0 g

• The other ingredients are:

glycerol,

egg lecithin,

all rac α -tocopherol,

sodium oleate

water for injections.

The amount of energy supplied per litre of Lipofundin MCT/LCT 20 % is 7990 kJ (1908 kcal).

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:

B. Braun Melsungen AG,

Carl-Braun-Str. 1

34212 Melsungen, Germany

Telephone: ++49-56 61-71-0

Fax: +49-56 61-71-45 67

Postal address,

34209 Melsungen, Germany

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The following information is intended for medical healthcare professionals only:

Before infusing this lipid emulsion together with other solutions via a Y connector or bypass set, the compatibility of these fluids will be checked, especially when given with carrier solutions containing other drugs. Special care has to be taken when infusing this product with other solutions containing certain electrolytes (such as calcium).

If the fat emulsion has been stored in a cool room or a refrigerator, it has to be allowed to warm up to room temperature before use.

If filters are used, these must allow the lipids (fat droplets) to pass through.

This emulsion has to be inspected before use and should not be administered if the emulsion has separated.

Emulsions that have been frozen must be discarded.



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