

Product Name: <b>LIPPVENÖS MCT 10%</b>		Territory: <b>ME</b>	Colour: <b>● BLACK</b>	1. Draft    07.08. 2015 07.26 Uhr	Variable Data:  <b>Batch no</b>  <b>Use before</b>
Type of Packaging: <b>PIL</b>	Dosage: <b>500ml</b>				
Material number: <b>M080171/00 ME</b>	2-D-Matrix Code <b>X</b>				
Pharma-Code (Laetus) <b>9427</b>	EAN Code:				
Dimension: <b>630 x 148 mm</b>	Font: <b>ARIAL</b> Smallest Size: 8 Pt.	Operator: <b>Christian Nagy +43(0) 34 52 72266-22</b>			

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Possible early reactions with the use of fat emulsions are:

Very rare: prolonged erection of the penis (priapism)

Frequency not known:

- slight increase in temperature
- feeling of heat, feeling of cold

- shivering
- rapid development of redness of the skin with a feeling of warmth (flush) or bluish discolouration (cyanosis)
- loss of appetite, nausea, vomiting;
- shortness of breath
- head, back, bone, chest and lower back pain
- increase or decrease in blood pressure (hypotension, hypertension)
- hypersensitivity reactions (e.g. anaphylactoid reactions, skin rash)

If these side effects occur or if triglyceride levels during the fat infusion exceed 3 mmol/l, the fat infusion must be stopped or, if necessary, the infusion continued at a reduced dose.

The administration of fat should also be stopped if a marked reactive increase in blood sugar occurs during the use of Lipovenös® MCT 10%. In the event of a massive overdose when carbohydrates are not being taken at the same time, excessive acidification of the blood (metabolic acidosis) can occur.

This medicine contains soybean oil and egg phospholipids, which in very rare cases can cause allergic reactions. The possibility cannot be ruled out that, if you are hypersensitive to peanuts, you will also experience a hypersensitivity reaction to the soybean oil contained in this product (allergic cross-reaction).

Attention should be paid to the possibility of fat overload syndrome. This can develop at different rates and after different doses because of genetically determined, individually different metabolic conditions and in association with different previous illnesses.



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Fat overload syndrome is associated with the following symptoms:

- enlargement of the liver (hepatomegaly) with and without jaundice (icterus)
- enlargement of the spleen (splenomegaly)
- diseased (pathological) liver function samples
- iron deficiency of the blood (anaemia), reduction in white blood cells (leukopenia)
- reduction in blood platelets (thrombocytopenia)
- tendency to bleeding and bleeds
- change, for instance reduction in blood coagulation factors (bleeding time, clotting time, prothrombin time, etc.)
- increased blood fat levels (hyperlipidaemia)
- fever, headache, stomach ache, tiredness

#### Additional side effects in children

In newborn babies and infants, the bile pigment bilirubin can be displaced from its binding to albumin when lipid emulsions are used, particularly by long-chain triglycerides. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### 5. How to store Lipovenös® MCT 10%

Keep this medicine out of the sight and reach of children

Do not use the medicine after the expiry date which is stated on the label and outer carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze.

Opened containers are intended for immediate use. Discard any unused infusion emulsion after use. Do not use this medicine if the container is damaged or if the emulsion does not have a homogeneous milky appearance.

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#### 6. Contents of the pack and other information

What Lipovenös® MCT 10% contains

- The active substances are: soybean oil, medium-chain triglycerides, glycerol and egg phospholipids. 1000 ml emulsion contains:

Soybean oil	50.0 g
(content of essential fatty acids:	
linoleic acid (18: 2 ω 6) 23.04 – 27.84 g	
α-linolenic acid (18: 3 ω 3) 2.4 – 5.28 g	
Medium-chain triglycerides (MCT)	50.0 g
Glycerol	25.0 g
Egg phospholipids	6.0 g
(4.50 – 4.86 g (3-sn-phosphatidyl)choline)	

- The other ingredients are:  
sodium oleate  
sodium hydroxide  
water for injections

Total energy	4300 kJ/l = 1030 kcal/l
pH	6.5 – 8.8
Titration acidity	< 1.0 mmol HCl/l or 1.0 mmol NaOH/l
Theoretical osmolarity	272 mosm/l

#### What Lipovenös® MCT 10% looks like and contents of the pack:

Lipovenös® MCT 10% is a homogeneous, milky fluid (emulsion).

#### Lipovenös® MCT 10% is available in the following pack sizes:

100 ml, 250 ml and 500 ml glass bottles

#### Marketing Authorisation Holder and Manufacturer

Fresenius Kabi Deutschland GmbH  
D – 61346 Bad Homburg v.d.H.  
Tel.: 06172 / 686 - 8200

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#### Manufacturer:

Fresenius Kabi Austria GmbH  
Hafnerstraße 36  
A – 8055 Graz

The following information is intended for healthcare professionals only:

Incompatibilities, particularly in combination with heparin, can occur as a result of the addition of polyvalent cations (e.g. calcium). A mixture of Lipovenös® MCT 10% with other infusion solutions, electrolyte concentrates or drugs is only permitted if it has been ensured that the solutions are compatible.

Lipovenös® MCT 10% must on no account be stored after the addition of other components.

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M080171/00 ME

Package leaflet: Information for the user

## Lipovenoes 10% MCT/LCT

Emulsion for infusion

**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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### What is in this leaflet

1. What Lipovenös® MCT 10% is and what it is used for
2. What you need to know before you use Lipovenös® MCT 10%
3. How to use Lipovenös® MCT 10%
4. Possible side effects
5. How to store Lipovenös® MCT 10%
6. Contents of the pack and other information

#### 1. What Lipovenös® MCT 10% is and what it is used for

- Lipovenös® MCT 10% is a fat emulsion for parenteral nutrition, i.e. that is given to you via a vein (IV drip).
- Lipovenös® MCT 10% is used to meet the body's energy requirements with a rapidly convertible fat component (MCT) and to provide vital fatty acids that the body itself cannot produce (essential fatty acids). Lipovenös® MCT 10% is given to you as part of a parenteral nutrition regime, a form of nutrition that by-passes the digestive tract. You receive Lipovenös® MCT 10% if the normal intake of food by mouth or tube feeding (oral or enteral nutrition) is impossible, insufficient or contra-indicated.



You must talk to a doctor if you do not feel better or if you feel worse.

## 2. What you need to know before you use Lipovenös® MCT 10%

### Do not use Lipovenös® MCT 10%

- if you are allergic to egg, soya or peanut protein, soybean oil, medium-chain triglycerides (MCT fat), glycerol, egg phospholipids or any of the other ingredients of this medicine (listed in section 6)
- if you have severe blood clotting disorders
- if you have been diagnosed with a circulatory collapse or a life-threatening disorder of the blood circulation (states of shock and collapse)
- during pregnancy
- if you have been diagnosed with an acute blockage of a blood vessel by a blood clot (acute thromboembolic events)
- if you have severe blood poisoning with excessive acidification of the blood and oxygen deficiency (severe septic states with acidosis and hypoxia)
- if you have been diagnosed with an obstruction of a blood vessel due to the infiltration of fatty droplets (fat embolism)
- during the acute phase of a heart attack or stroke

- if you have been diagnosed with a severe loss of blood sugar control with excessive acidification of the blood and loss of consciousness (acidophilic coma)
- if you have diabetes and you have been diagnosed with a metabolic state that immediately precedes a loss of consciousness (diabetic precoma)
- if you have excessive acidification of the blood (acidosis of varying origin)
- if you have untreated disorders of the salt and fluid balance in the form of salt and water deficiency (hypotensive dehydration), reduced potassium levels in the blood serum (hypokalaemia) and/or excess fluid (hyperhydration)
- if your metabolism is not stable
- if you have an obstruction of the bile originating in the liver (intrahepatic cholestasis)

Additionally, in the event of a build-up of a particular blood fat (triglyceride accumulation) during the use of Lipovenös® MCT 10 %:

- if you have fat metabolism disorders
- if you have a severe impairment of liver function (hepatic insufficiency)
- if you have a severe impairment of kidney function (renal insufficiency)
- if you have certain diseases of the immune system affecting the "reticuloendothelial system" (RES diseases)
- if you have an acute inflammation of the pancreas with internal bleeding and tissue destruction (acute haemorrhagic necrotising pancreatitis)

### Warnings and precautions

Serum triglycerides must be monitored daily and blood sugar, acid-base balance, electrolyte status, fluid input and output, and blood count at appropriate intervals. Serum triglyceride levels should not exceed 3 mmol/l during an on-going fat infusion.

There are indications that peroxide formation in the infusion solution cannot be completely ruled out during phototherapy if fat emulsions are administered at the same time due to the effect of light.

### Children and adolescents

Therefore, as a precaution it is recommended that the fat emulsion should be protected from the effect of light in newborn infants receiving phototherapy.

### Other medicines and Lipovenös® MCT 10%

Tell your doctor or pharmacist if you are taking or using, have recently taken or used or might take or use any other medicines.

For information about incompatibilities, see section "The following information is intended for healthcare professionals only".

### Pregnancy, breast-feeding and fertility

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 using this medicine.

Lipovenös® MCT 10% must not be used during pregnancy (see section 2 under "Do not take Lipovenös® MCT 10%").

### Driving and using machines

You will usually receive Lipovenös® MCT 10% in hospital or under other medical supervision, in other words under conditions that rule out driving or using machines.

### Lipovenös® MCT 10% contains sodium compounds.

Each 100 ml bottle contains sodium, but less than 1 mmol (23 mg), i.e. it is more or less "sodium-free".

Each 250 ml bottle of Lipovenös® MCT 10% contains up to 1.25 mmol (or 28.75 mg) sodium.

Each 500 ml bottle of Lipovenös® MCT 10% contains up to 2.5 mmol (or 57.5 mg) sodium.

You must bear this in mind if you are required to follow a low-salt diet.

### 3. How to use Lipovenös® MCT 10%

Your doctor will decide the dose for you individually according to your body weight and state of health. Lipovenös® MCT 10% is given to you by your doctor or by the nursing staff.

The recommended dose is

The maximum daily dose should be administered only after the dose has been gradually increased and with close monitoring of the tolerability.

Depending on the calorie requirement, the dose given is:

Adults

1 - 2 g fat/kg body weight (b.w./day), corresponding to 10 - 20 ml Lipovenös® MCT 10 %/kg b.w./day.

Infusion or drip rate

In principle, fat emulsions should be infused slowly and as evenly as possible. Particularly during the first 15 minutes of a fat infusion,

the infusion rate should not exceed 0.05 - 0.1 g fat/kg b.w./hour, corresponding to 0.5 - 1.0 ml/kg b.w./hour for Lipovenös® MCT 10%.

Maximum infusion rate

up to 0.15 g fat/kg b.w./hour, corresponding to 1.5 ml Lipovenös® MCT 10 %/kg b.w./hour.

Maximum drip rate

For Lipovenös® MCT 10%, up to 0.5 drops/kg b.w./minute.

This is equivalent to an infusion rate of about 100 ml/hour or a drip rate of up to 35 drops/minute in a patient weighing 70 kg.

In malnourished patients, the drip rate should be reduced in line with body weight.

Total fluid intake should exceed 40 ml/kg b.w. only in exceptional circumstances.

It is recommended to choose an infusion rate such that the planned daily dose is administered within 24 hours, but at least 16 hours/day.

### Children and adolescents

Newborns

2 - 3 g (max. 4 g) lipid/kg b.w./day, corresponding to 20 - 30 ml (max. 40 ml) Lipovenös® MCT 10 %/kg b.w./day.

Since the ability to eliminate triglycerides and lipids is not always fully matured, particularly in premature and low-birth-weight infants, the recommended dosages should be used only if serum triglycerides are closely monitored. Hyperlipidaemia must be avoided.

Infants and young children

10 - 30 ml Lipovenös® MCT 10%/kg b.w./day

Schoolchildren

1 - 2 g fat/kg body weight (b.w./day), corresponding to 10 - 20 ml Lipovenös® MCT 10 %/kg b.w./day.

Infusion or drip rate

In principle, fat emulsions should be infused slowly and as evenly as possible. Particularly during the first 15 minutes of a fat infusion, the infusion rate should not exceed 0.05 - 0.1 g fat/kg b.w./hour, corresponding to 0.5 - 1.0 ml/kg b.w./hour for Lipovenös® MCT 10%.

Maximum infusion rate

Up to 0.15 g fat/kg b.w./hour, corresponding to 1.5 ml Lipovenös® MCT 10 %/kg b.w./hour.

Maximum drip rate

For Lipovenös® MCT 10% up to 0.5 drops/kg b.w./minute.

In children, the drip rate must be reduced in line with body weight.

Total fluid intake should exceed 40 ml to 100 ml/kg, according to need (age), only in exceptional circumstances.

It is recommended to choose an infusion rate such that the planned daily dose is administered within 24 hours, but at least 16 hours/day.

Method of administration

Lipovenös® MCT 10% is given via a vein (intravenous administration. For peripheral venous infusion).

Amino acids and carbohydrates should be administered at the same time as a fat emulsion as part of a parenteral nutrition regime.

Lipovenös® MCT 10% is used for as long as parenteral nutrition is required.

Lipovenös® MCT 10% is administered simultaneously with amino acid solutions and/or carbohydrate solutions via separate infusion systems and veins. If the infusion is given via a common final infusion line (by-pass, Y-connector), the compatibility of both solutions must be ensured.

The use of filters with a pore size of 0.2 µm is not possible, as fat emulsions do not pass through these filters.

Infuse emulsions of room temperature only.

Shake before use.

### If you receive more Lipovenös® MCT 10% than you should

Overdosage (triglyceride levels exceeding 3 mmol/l or 270 mg/dl during an on-going infusion) may lead to the symptoms mentioned under the "side effects" section. In this event, the fat infusion must be stopped or, if necessary, continued at a reduced dose.

The administration of fat should also be stopped if a marked reactive increase in blood sugar occurs during the use of Lipovenös® MCT 10%. In the event of a massive overdose when carbohydrates are not being taken at the same time, excessive acidification of the blood (metabolic acidosis) can occur.

### If it is forgotten to use Lipovenös® MCT 10%

If it is forgotten to use this medicine, your doctor will decide how to proceed.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### 4. Possible side effects

Side effects can occur as symptoms of an overdose, see section 3 under "If you take more Lipovenös® MCT 10% than you should".

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In assessing side effects, the following convention has been used for classifying frequency:

Very common:	more than 1 in 10 patients treated
Common:	1 to 10 in 100 patients treated
Uncommon:	1 to 10 in 1,000 patients treated
Rare:	1 to 10 in 10,000 patients treated
Very rare:	less than 1 in 10,000 patients treated
Not known:	cannot be estimated from the available data