418/12605301/0117

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Lipids with Omega-3

1000 ml of emulsion contains	
Medium-chain triglycerides	100 g
Soya-bean oil	80.0 g
Omega-3-acid triglycerides	20 g

Lipidem

Emulsion for infusion
Parenteral Nutrition

Formulation
Active ingredients:

1000 mL emulsion contains:

Medium-chain triglycerides	100 g
Refined soya oil	80 g
Omega-3-acid triglycerides	20 g

The other ingredients are:
Egg lecithin, glycerol, sodium oleate, palmitoyl ascorbic acid, alpha-tocopherol, sodium hydroxide for pH adjustment, water for injections.

Essential fatty acid content per litre:

Linoleic acid (omega-6)	48 - 58 g
α-linolenic acid (omega-3)	5 - 11 g
Eicosapentaenoic acid and docosahexaenoic acid (omega-3)	8.6 - 17.2 g
Energy content per litre	7900 kJ ≙ 1910 kcal
Osmolality approx.	410 mOsm/kg
Titratable acidity/alkalinity (to pH 7.4)	< 0.5 mmol/L NaOH or HCl
pH:	6.5 - 8.5

Substance and indication group or mode of action
Fat emulsion for calorie replacement with rapidly metabolisable fat constituents (medium-chain triglycerides) and for supplying essential fatty acids.

Therapeutic indications
For the supply of fats, including essential omega-6 fatty acids and omega-3 fatty acids, as part of a parenteral nutrition regimen in adults if oral or enteral nutrition is impossible, inadequate or contraindicated.

Contraindications
Lipidem must not be used in the following circumstances:
- severe hyperlipidaemia (abnormally high levels of fats in the blood)
- severe blood clotting disorders
- blockage of bile flow in the liver (intrahepatic cholestasis)
- severely impaired liver function (severe liver failure)
- severely impaired kidney function (severe kidney failure) without access to haemofiltration or dialysis
- patients in the acute phase of a heart attack or a stroke
- acute thromboembolic disease, fat embolism (blockage of a blood vessel by a blood clot or fat)
- hypersensitivity to egg, fish or soya protein or to the pharmacologically active ingredients or any of the other ingredients.

General contraindications to infusion therapy:
- life-threateningly unstable circulatory situations (states of collapse and shock)
- unstable metabolism (e.g. after major surgery or serious injuries, uncontrolled diabetes, severe systemic infection (sepsis), excessive blood acidity (acidosis)
- acute fluid accumulation in the lung (pulmonary oedema)
- overhydration
- severely impaired cardiac function
- fluid loss and excessive salt loss (hypotonic dehydration)
- low potassium concentration in the blood (hypokalaemia)

Use in children and adolescents
Safety and efficacy in children and adolescents have not been proven. No clinical experience is available.

Precautions for use and warnings
Blood fat concentrations (serum triglycerides) should be closely monitored during infusion of Lipidem. Fasting lipaemia (abnormally high blood fat concentration in the fasting state) should be ruled out in patients with suspected disorders of fat metabolism before commencing infusion. Hypertriglyceridaemia (abnormally high blood fat concentration) persisting 12 hours after the fat infusion is also an indication of a disorder of fat metabolism.

Depending on the patient's metabolic state, hypertriglyceridaemia or elevated blood sugar levels may transiently occur. If the triglyceride concentration in the plasma increases during infusion of the fat emulsion to over 3 mmol/L, it is advisable to reduce the infusion rate. If the triglyceride concentration in the plasma is then still over 3 mmol/L, the infusion should be suspended until plasma triglycerides have returned to normal.
Serum electrolytes, fluid balance or body weight, acid-base balance, blood sugar levels and, if used long-term, full blood count, clotting status and liver function should be monitored.
There is only limited experience of use of Lipidem in patients with diabetes or kidney failure.
There is only limited experience of use of Lipidem for periods of more than seven days.
Infusion of Lipidem should be suspended if signs of an allergic reaction occur, e.g. fever, shivering, a rash, shortness of breath.
Overdose may lead to a fat overload syndrome (see also the "Usage errors and overdose" and "Side effects" sections).
Caution is necessary in diseases with disorders of fat metabolism such as kidney failure, diabetes, inflammation of the pancreas (pancreatitis), liver failure, impaired thyroid function (in the context of hypertriglyceridaemia) and sepsis.
Lipids may affect certain laboratory parameters (e.g. bilirubin, lactate dehydrogenase, oxygen saturation, haemoglobin measurement) if the blood samples are collected before elimination of lipids (removal of fats) from the bloodstream has taken place. This is complete 5 - 6 h after the end of the infusion in the majority of patients.
If fat emulsions are used as the sole supply of energy, metabolic acidosis (excessive blood acidity) may occur. This can be prevented by simultaneous infusion of carbohydrates. Infusion of a sufficient quantity of a carbohydrate solution or a carbohydrate-containing amino acid solution, in addition to the fat emulsion, is therefore advisable.
Vitamin E may affect the action of vitamin K in the formation of clotting factors. This should be borne in mind in patients with clotting disorders or suspected vitamin K deficiency.

Important warnings about some ingredients of Lipidem
Lipidem contains 2.6 mmol/L sodium. This should be taken into account if the patient has to keep to a low-salt diet.

Pregnancy and lactation
There is no experience of use of Lipidem during pregnancy.
Parenteral nutrition may be necessary during pregnancy. Lipidem should be given to pregnant women only after carefully weighing up the risks and benefits, however.
There is likewise no experience of use of Lipidem while breast-feeding.
It is not currently known whether the active substances in Lipidem are secreted in breast milk.
As a general rule, it is inadvisable for mothers to breast-feed if they are being fed parenterally.

Interactions with other medicinal products
Heparin brings about short-term release into the blood stream of an enzyme that breaks down fat (lipoprotein lipase). This may initially lead to increased breakdown of fat (lipolysis) in the plasma, followed by a transient reduction in clearance of triglycerides.
Soya oil naturally contains vitamin K_1. Levels in Lipidem are so low, however, that there is unlikely to be any detectable effect on the clotting process of patients who are being treated with medicines to prevent the blood clotting (coumarin derivatives). Clotting status should nevertheless be monitored in patients who are being treated with such medicines.

Posology and method of administration
The dosage should be individually adjusted to the particular patient's needs.

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Adults:
Recommended dosage:
1-2 g fat per kg body weight per day
equivalent to 5 - 10 ml Lipidem per kg body weight per day

Infusion rate:
The infusion should be given at the lowest possible rate. For the first 15 minutes, the infusion rate should be only 50% of the maximum usable infusion rate.

Maximum infusion rate:
up to 0.15 g fat per kg body weight per hour,
equivalent to up to 0.75 mL Lipidem per kg body weight per hour.

The infusion rate should be reduced in malnourished patients.

Since there is only limited experience of long-term use of Lipidem, the medicine should not normally be used for longer than one week.
The emulsion may be used for longer periods only if careful consideration has been given to the need for treatment and with close monitoring of the patient's metabolism.

Method of use:
Lipidem is suitable for central and peripheral intravenous infusion.
Since no compatibility studies have been performed, this medicine must not be mixed with other medicines.
Before infusing a fat emulsion simultaneously with other solutions via a three-way stopcock or a secondary tubing connector, the miscibility (compatibility) of these infusion solutions should be checked, particularly if carrier solutions mixed with active substances are to be infused at the same time. Particular caution is necessary on simultaneous administration of solutions containing divalent electrolytes (e.g. calcium).
The emulsion should not be used unless it is homogeneous and the container is undamaged. The emulsion should be visually checked for phase separation before use.
The emulsion should always be brought to room temperature before infusion.
If filters are used, these must be fat-permeable.

Overdose
Overdose, leading to a fat overload syndrome, may occur with too high an infusion rate or with prolonged use at the recommended infusion rate in association with a change in the patient's clinical state, e.g. impaired kidney function or infection. Overdose may lead to side effects (see also "Side effects" section).
Substantial overdose of a fat emulsion containing medium-chain triglycerides may lead to metabolic acidosis, particularly if carbohydrates are not given simultaneously.
Treatment: in the event of overdose, the infusion should be stopped immediately. Additional treatment measures depend on the nature and severity of the symptoms in each individual case. If the infusion is restarted once the symptoms have resolved, the infusion rate should be increased only slowly and with careful monitoring of the patient.

Undesirable effects
Evaluation of side effects is based on the following frequencies:
Very common: more than 1 per 10 subjects treated
Common: less than 1 per 10 but more than 1 per 100 subjects treated
Uncommon: less than 1 per 100 but more than 1 per 1,000 subjects treated
Rare: less than 1 per 1,000 but more than 1 per 10,000 subjects treated
Very rare: less than 1 per 10,000 subjects treated, including isolated cases

The side effects mentioned below include a number of systemic reactions that occur very rarely in association with use of Lipidem.

Blood and lymphatic system disorders
Very rare: hypercoagulation (increased tendency of the blood to clot)

Immune system disorders
Very rare: allergic reactions

Metabolism and nutrition disorders
Very rare: hyperlipidaemia, hyperglycaemia (abnormally high blood sugar level), metabolic acidosis (excessive acidity of metabolic origin), ketoacidosis.
The occurrence of the side effects listed here is dose-dependent. They are highly likely to occur as symptoms of absolute or relative overdose. The frequencies stated above relate to correct use in terms of dosage, dose monitoring and compliance with safety information and directions for use.

Central and peripheral nervous system disorders
Very rare: drowsiness

Vascular disorders
Very rare: high or low blood pressure (hypertension or hypotension)

Respiratory, thoracic and mediastinal disorders
Very rare: shortness of breath, bluish discoloration of the skin (cyanosis)

Gastrointestinal disorders
Very rare: nausea, vomiting

General disorders and/or administration site conditions
Very rare: headache, (inflammatory) redness, raised body temperature, bouts of sweating, shivering, chest and back pain, fat overload syndrome (see below).
Should these side effects occur or should triglyceride levels during the infusion exceed 3 mmol/L, infusion of Lipidem should be suspended or, if necessary, continued at a reduced dosage.
If the infusion is restarted, the patient should be carefully monitored, particularly at the start, and serum triglycerides should be checked at short intervals.
Triglycerides containing omega-3 fatty acids may cause prolongation of bleeding time and inhibition of blood platelet function (platelet aggregation). Furthermore, a deterioration in lung function may occur in patients with asthma triggered by acetylsalicylic acid.
Lipidem should always be part of a complete parenteral nutrition regimen with amino acids and glucose. Nausea, vomiting, loss of appetite and hyperglycaemia may be side effects of diseases that necessitate parenteral nutrition or they may occur in connection with parenteral nutrition.

Fat overload syndrome
Reduced capacity for excretion of triglycerides may lead to a fat overload syndrome that may be caused by overdose. Patients must therefore be monitored for possible signs of overdose. Its occurrence may be genetically determined (differences in metabolism from one individual to another) or else fat metabolism is impaired by current or past diseases. This syndrome may also occur in the context of severe hypertriglyceridaemia even at the recommended infusion rate in association with a dramatic deterioration in the patient's clinical state, such as impaired kidney function or infections. Fat overload syndrome is characterised by hyperlipaemia, fever, fatty deposits, hepatomegaly (enlargement of the liver) with or without jaundice, splenomegaly (swelling of the spleen), anaemia, a reduced number of white blood cells and blood platelets (leukopenia, thrombocytopenia), clotting disorders, destruction of red blood cells (haemolysis) and reticulocytosis (a change in the blood count), abnormal liver test results and unconsciousness. The symptoms are normally reversible if infusion of the fat emulsion is stopped. Should signs of a fat overload syndrome occur, the infusion should be stopped immediately.

Instructions for storage / use / handling
Do not use the medicine after the expiry date which is stated on the container and the carton.
Keep out of the reach and sight of children.
Use immediately after opening.
Store at temperatures not exceeding 25°C. Store in the original package in order to protect from light. Do not freeze.
Emulsion that has been frozen should be discarded.
Do not use the emulsion unless it is homogeneous and the container is undamaged.
Check the emulsion visually for signs of phase separation before use.
For single use only. Any unused emulsion should be discarded.

Availability
Emulsion for infusion in glass bottles in packs of 10 x 100 mL, 10 x 250 mL and 10 x 500 mL

Reg. no. : DR-XY35761

Caution
Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of any adverse drug reaction.

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