

SMOFLIPID 20%

Forms and presentation

White homogenous emulsion for infusion
Bottles of 250 ml and 500 ml.

Composition

1 liter of emulsion contains:

Soya-bean oil, refined	60 g	
Triglycerides, medium-chain	60 g	
Olive oil, refined		50 g
Fish oil, rich in omega-3-acids	30 g	
Total energy: 2000 Kcal/l		
pH-value: approx. 8		
Osmolality: approx. 380 mosom/kg		

Indications

Supply of energy and essential fatty acids and omega-3 fatty acids to patients, as part of a parenteral nutrition regimen, when oral or enteral nutrition is impossible, insufficient or contra-indicated.

Contraindications

Hypersensitivity to fish-egg, soya or peanut protein or to any of the active substances or excipients.
Severe hyperlipidemia, severe liver insufficiency, severe blood coagulation disorders, severe renal insufficiency without access to hemofiltration or dialysis.
Acute shock
General contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency
Unstable conditions (e.g. severe post-traumatic conditions, uncompensated diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis and severe sepsis and hypotonic dehydration).

Precautions

The capacity to eliminate fat is individual and should therefore be monitored according to the routines of the clinician. This is in general done by checking the triglyceride levels. Special caution should be taken in patients with a marked risk for hyperlipidemia (e.g. patients with high lipid dosage, severe sepsis and extremely low birth weight infants). The concentration of triglycerides in serum should in general not exceed 3 mmol/l during infusion. Reduction of the dosage or cessation of the lipid emulsion should be considered if serum or plasma triglyceride concentrations during or after infusion exceed 3 mmol/L. An overdose may lead to fat overload syndrome.

Drug interactions

Heparin given in clinical doses causes a transient increase in lipoprotein lipase release into the circulation. This may initially result in increased plasma lipolysis, followed by a transient decrease in triglyceride clearance.
Soya-bean oil has a natural content of vitamin K1. The content is however so low in Smoflipid that it is not expected to significantly influence the coagulation process in patients treated with coumarin derivatives.

Dosage and administration

Adults: 1 – 2 g/kg body weight/day = 5 – 10 ml/kg body weight/day
Maximum dosage: 0.15 g/Kg body weight/hour = 0.75 ml/Kg body weight/hour

Neonates and infants:

The initial dose should be 0.5 – 1 g/kg body weight/day followed by a successive increase by 0.5 – 1 g/kg body weight/day up to 3 g/kg body weight/day.

It is recommended not to exceed a daily dose of 3 g fat/kg body weight/day = 15 ml/kg body weight/day.

The rate of infusion should not exceed 0.125 g/kg body weight/hour.

In premature and low birthweight neonates, Smoflipid should be infused continuously over about 24 hours.

Children: It is recommended not to exceed a daily dose of 3 g fat/kg body weight/day = 15 ml/kg body weight/day.

The daily dose should be increased gradually during the first week of administration.

The infusion rate should not exceed 0.15 g/kg body weight/hour.

Administration: Intravenous infusion into a peripheral or central vein.

Undesirable effects

Dyspnea, lack of appetite, nausea, vomiting, hypotension, hypertension, slight increase in body temperature, chills, priapism, hypersensitivity reactions (e.g. anaphylactic or anaphylactoid reactions, skin rash, urticarial, flush, headache); heat or cold sensation; paleness; cyanosis; pain in the neck, back, bones, chest and loins

Shelf life after first opening the container: Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view the emulsion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C.

Storage

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

Storage after mixing: If additions are made to Smoflipid, the admixtures should be used immediately from a microbiological point of view. If admixtures are not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless additions have taken place in controlled and validated aseptic conditions.