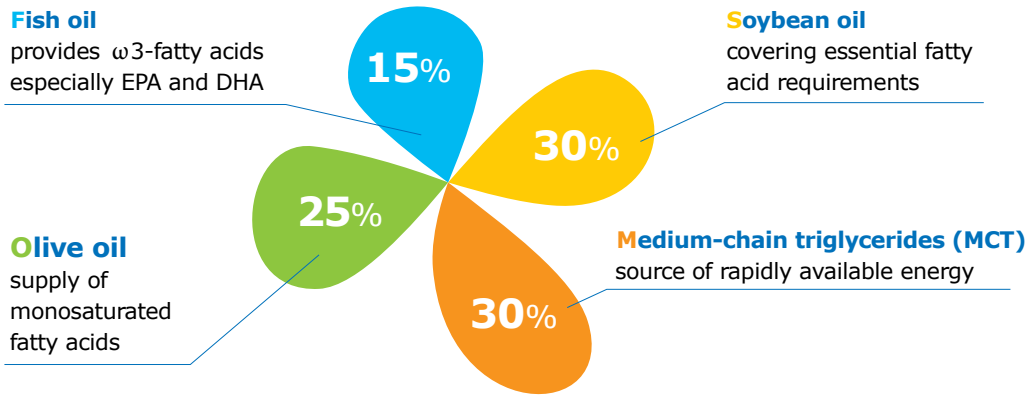
FRESENIUS KABI
caring for life

SMOFlipid®

The link to health benefits

SMOFlipid® – a unique, well balanced 4-oil mix with purified fish oil



+ additional vitamin E (approx. 200 mg α-tocopherol/L)
to counteract lipid peroxidation and oxidative stress

Abbreviated Prescribing Information - SMOFlipid®200mg/ml, Emulsion for Infusion.

Consult the Summary of Product Characteristics for full information. Additional information is available on request.

Active ingredients: 1000ml contains: Soya-bean oil (refined) 60g, Medium-chain triglycerides 60g, Olive oil (refined) 50g, Fish oil (rich in omega-3-acids) 30g. 1000ml emulsion contains up to 5mmol sodium. **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 contraindicated. **Dosage and administration:** Intravenous infusion into a peripheral or central vein. The dosage and infusion rate should be governed by the patient's ability to eliminate fat. Adults standard dose is 1.0–2.0g fat/kg body weight (bw)/day (5–10 ml/kg bw/day). Recommended infusion rate is 0.125g fat/kg bw/hour and should not exceed 0.15g fat/kg bw/hour, corresponding to 0.75ml SMOFlipid/kg bw/hour. Children infusion rate should not exceed 0.15g fat/kg bw/hour. Increase daily dose gradually over the first week of administration. The maximum recommended daily dose is 3g fat/kg bw/day, corresponding to 15ml SMOFlipid/kg bw/day. Neonates and infants initial dose should be 0.5–1.0g fat/kg bw/day followed by a successive increase of 0.5–1.0g fat/kg/bw/day up to 3.0g fat/kg bw/day (corresponding to 15ml SMOFlipid/kg bw/day). The infusion rate should not exceed 0.125g fat/kg bw/hour. In premature and low birthweight neonates, infuse SMOFlipid continuously over about 24 hours. Administer as part of a complete parenteral nutrition treatment including amino acids and glucose. When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. **Contraindications:** Hypersensitivity to fish-, egg-, soya- or peanut protein, or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, general contraindications to infusion therapy, unstable conditions (see SmPC). **Special warnings and precautions for use:** Monitor individual's capacity to eliminate fat. Dose reduction or cessation of infusion should be considered if serum or plasma triglyceride concentrations during or after infusion exceed 3mmol/L. Use with caution in conditions of impaired lipid metabolism, in patients with marked risk for hyperlipidemia, in neonates and premature neonates with hyperbilirubinemia and/or pulmonary hypertension. Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been seen between soya-bean and peanut. Administration of medium-chain fatty acids alone can result in metabolic acidosis; simultaneous infusion of carbohydrate or a carbohydrate-containing amino acid solution is recommended. Laboratory tests generally associated with monitoring of intravenous nutrition should be checked regularly. Monitor blood platelet counts, liver function tests and serum triglycerides in neonates. Any sign or symptom of anaphylactic reaction should lead to immediate interruption of the infusion. High plasma lipid levels may interfere with some laboratory blood tests. **Undesirable effects:** Common – slight increase in body temperature. Uncommon – lack of appetite, nausea, vomiting, chills. Rare – hypotension, hypertension, dyspnoea, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Very rare – priapism. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Number:** UK:PL 08828/0166. IE: PA566/35/1-2. **Marketing Authorisation Holder:** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. **Package Size and Cost:** UK: 100ml £7.44, 250ml £11.90, 500ml - £17.43. **Further information:** Prescribers should consult the summary of product characteristics in relation to **other adverse reactions. Adverse events should be reported** at https://yellowcard.mhra.gov.uk. For Ireland, adverse adverts should be reported via HPRA pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6762517. Website: www.hpra.ie; Email:med-safety@hpra.ie. Adverse events should also be reported to Fresenius Kabi at Pharmacovigilance. GB@fresenius-kabi.com.

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