Abbreviated SPC

INTRALIPID 20%

QUALITATIVE AND QUANTITATIVE COMPOSITION
1000 ml of the emulsion contains: Purified soybean oil 200 g. Osmolality: 350 mosm/kg water. pH approx. 8. Energy content: 8.4 MJ (2000 kcal) /1000 ml. Organic phosphate content: 15 mmol/1000ml.

THERAPEUTIC INDICATION
Intralipid is indicated in patients needing intravenous nutrition to supply energy and essential fatty acids. Intralipid is also indicated in patients with essential fatty acid deficiency (EFAD) who cannot maintain or restore a normal essential fatty acid pattern by oral intake.

POSOLOGY AND METHOD OF ADMINISTRATION
The ability to eliminate Intralipid should govern the dosage and infusion rate. See below **Fat elimination.** Dosage: 1g triglycerides corresponds to 5 ml Intralipid 20%. Adults: The recommended maximum dosage is 3 g triglycerides/ kg body weight/day. Within this upper limit, Intralipid can be given to contribute up to 70% of the energy requirements, also in patients with highly increased energy requirements. The infusion rate for Intralipid 20% should not exceed 500 ml in 5 hours. Neonates and infants: The recommended dosage range in neonates and infants is 0.5-4 g triglycerides/ kg bw/day. The rate of infusion should not exceed 0.17 g triglycerides/kg bw/hour (4 g in 24 hours). In prematures and low birthweight neonates, Intralipid should preferably be infused continuously over 24 hours. The initial dosage should be 0.5-1 g/kg bw/day followed by a successive increase by 0.5-1 g/kg bw/day up to 2g/kg bw/day. Only with close monitoring of serum triglyceride concentration, liver tests and oxygen saturation may the dosage be increased to 4 g/kg bw/day. The rates given are maximum rates and no attempt should be made to exceed these in order to compensate for missed doses. Essential fatty acid deficiency (EFAD): To prevent or correct essential fatty acid deficiency, 4 to 8% of the nonprotein energy should be supplied as Intralipid to provide sufficient amounts of linoleic and linolenic acid. When EFAD is associated with stress, the amount of Intralipid needed to correct the deficiency may be substantially increased. FAT ELIMINATION: Adults: The ability to eliminate fat should be closely monitored in patients with conditions mentioned in section 4.4, “Special warnings and special precautions for use”, and in patients given Intralipid for more than one week. This is done by collecting a blood sample after a fat-free clearance period of 5-6 hours. Blood cells are then separated from plasma by centrifugation. If the plasma is opalescent, the infusion should be postponed. The sensitivity of this method is such that hypertriglyceridaemia can pass undetected. Therefore, it is recommended that serum triglyceride concentrations should be measured in patients who are likely to have impaired fat tolerance. Neonates and infants: The ability to eliminate fat should be tested regularly in neonates and infants. Measuring serum triglyceride levels is the only reliable method.

CONTRAINDIATIONS
Intralipid is contraindicated in patients with acute shock and in patients with severe hyperlipemia. Severe liver insufficiency. Hemophagocytotic syndrome. Hypersensitivity to egg-, soya- or peanut protein or to any of the active substances or excipients.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE
Intralipid should be given with caution in conditions of impaired lipid metabolism as in renal insufficiency, uncompensated diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (if hypertri-glyceridemic) and sepsis. If Intralipid is given to patients with these conditions, close monitoring of the serum triglyceride concentration is obligatory. This medicinal product contains soya-bean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reactions have been observed between soybean and peanut. Intralipid should be given with caution to neonates and prematures with hyperbilirubinemia and cases with suspected pulmonary hypertension. In neonates, particularly prematures on long term parenteral nutrition, platelet count, liver test and serum triglyceride concentration should be monitored. Intralipid may interfere with certain laboratory measurements (bilirubin, lactate

dehydrogenase, oxygen saturation, Hb etc) if blood is sampled before fat has been adequately cleared from the blood stream. Fat is cleared after a fat free interval of 5-6 hours in most patients.

UNDESIRABLE EFFECTS

Intralipid infusion may cause a rise in body temperature and, less frequently, shivering, chills and nausea/vomiting (incidence<1%). Reports of other adverse events in conjunction with Intralipid infusion are extremely rare, less than one adverse event per one million infusions. Uncommon (>1/1000, <1/100), Very rare (<1/10 000): Body as a whole –
general disorders: uncommon: headache, rise in body temperature, shivering, chills, tiredness; very rare: anaphylactic reaction. Cardiovascular disorders: very rare: circulatory effects (e.g. hyper/hypotension). Gastrointestinal disorders: uncommon: abnormal pain, nausea, vomiting. Liver & biliary system disorders: very rare: transient increase in liver function test. Musculoskeletal, connective tissue and bone disorders: very rare: abdominal pain. Platelet, bleeding & clotting disorders: Very rare: thrombocytopenia. Red blood cell disorders: very rare: haemolysis, reticulocytosis. Reproductive disorders, male: very rare: priapism. Skin and appendages disorders: very rare: rash, urticaria.
Trombocytopenia has been reported in association with prolonged treatment with Intralipid in infants. Transient increase in liver function tests after prolonged intravenous nutrition with or without Intralipid have also been noted. The reasons are not clear at present. Fat overload syndrome. An impaired capacity to eliminate Intralipid may lead to the fat overload syndrome as a result of overdosage. However, this syndrome may appear also at recommended rates of infusion in association with a sudden change in the patient's clinical condition, such as renal function impairment or infection. The fat overload syndrome is characterised by hyperlipaemia, fever, fat infiltration and disorders in various organs and coma. All symptoms are usually reversible if the infusion of Intralipid is discontinued.

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