# For ROI healthcare professionals only

**PRESCRIBING INFORMATION – INTRALIPID® 20% EMULSION FOR INFUSION.** Consult the Summary of Product Characteristics for full information. Further information is available on request. **Active Ingredients:** Soya-bean oil refined, 20% w/v **Indications:** For the supply of caloric and essential fatty acids requirements in parenteral nutrition. **Dosage and administration:** Slow intravenous infusion. During first 10 minutes drip should be adjusted to 20 drops per minute then after half an hour of 25-40 drops per minute gradually increased to final rate. 500ml Intralipid 20% should be given over at least five hours. On the first day of infusion advisable to administer 5ml/kg bodyweight (bw). Dosage may be increased to a maximum of 3g fat/kg bw/24 hours. Can be given as a separate infusion or as part of an admixture (approved for physical stability). Dosage and infusion rate should be governed by the patient's ability to utilise fat and in line with the following ranges. *Adults* - 500-1500 ml per 24 hours in conjunction with amino acid and carbohydrate solutions. Essential fatty acid deficiency (EFAD) - 4-8% non-protein calories supplied as Intralipid for prevention or correction; substantially increase dose if EFAD associated with stress. *Elderly* - Caution in the 'frail' elderly and in all patients with poor renal, cardiac or liver function where smaller volumes should be used. *Infants* - Dosage is governed by the maturity and birth weight of the infant. Check daily infant's ability to eliminate infused fat through measurement of serum triglycerides. If lipaemia present retest after 4 hours. If possible, infuse continuously over 24 hours and use an appropriate pump to maintain constant infusion rate. *Infants* - 0.5-4.0 g fat/kg bw/24 hours (0.10-0.85 ml/kg/hour). Gradually increase dosage over the first week of administration. *Premature and low birth weight infants:* - Continuous infusion over 24 hours/day. Initially 0.5-1.0 g/kg/24 hours increasing by the same amount every 24 hours up to 2.0 g/kg/24 hours. Ensure concomitant careful monitoring of triglyceride levels, liver function tests and oxygen saturation. 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. Correct electrolyte, fluid, acid-base imbalance and shock prior to starting intravenous nutrition. In the seriously ill patient specific preliminary investigations and continuous monitoring are essential. Monitor vitamin and trace element levels especially in long-term intravenous nutrition. **Contraindications:** Hypersensitivity to egg, soya or peanut protein, or to any of the active substances or excipients, severe liver insufficiency, hemophagocytotic syndrome, and in patients with severe disorders of fat metabolism such as severe liver damage and acute shock. **Special warnings and precautions for use:** Correct shock, metabolic acidosis or severe dehydration before starting intravenous feeding. Aseptic technique should be adhered to; care to avoid infusion-related complications. Administer with amino acid and carbohydrate infusion to avoid acidosis. Use with caution in conditions of impaired lipid metabolism (check fat elimination daily), in newborns with neonatal hyperbilirubinaemia, and in infants with known or suspected pulmonary hypertension. Monitor platelet count, liver function tests and serum triglyceride concentration in neonates and particularly in prematures on long term parenteral nutrition. Contains soya-bean oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soybean and peanut. Closely monitor the elimination of fat in conditions of impaired lipid metabolism such as renal insufficiency, uncompensated diabetes mellitus, pancreatitis, certain forms of liver insufficiency, hypothyroidism, metabolic disorders, sepsis, and in neonates with conditions mentioned above and in patients given Intralipid for more than one week. 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. Intralipid may interfere with certain laboratory measurements if blood sampled before adequate fat clearance from bloodstream (see SmPC). **Undesirable effects:** In rare instances rise in temperature and less frequently shivering, chills and nausea/vomiting (discontinue Intralipid in such cases). Hypersensitivity reactions, respiratory symptoms, circulatory effects, haemolysis, reticulocytosis, abdominal pain, headache, tiredness and priapism have been reported. Increased levels of transaminases, alkaline phosphatase and bilirubin observed in patients receiving intravenous nutrition with or without Intralipid. Cholestasis also reported, and thrombocytopenia associated with prolonged Intralipid treatment in infants. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Marketing Authorisation Number:** Plastic: PA 2059/041/005. **Package size:** 10x100 ml, 10x250 ml and 12x500 ml. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** December 2024, IE-Int-2400004

**Adverse events should be reported.**
Reporting forms and information can be found at:
**www.hpra.ie/homepage/about-us/report-an-issue**
Adverse events should also be reported to Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT Tel +44 (0)1928 533 533.