CLINOLEIC 20%, EMULSION FOR INFUSION PRESCRIBING INFORMATION

Name and composition: ClinOleic 20%, Emulsion for Infusion, Each 1 litre contains Refined Olive Oil 160 g, Refined Soybean Oil 40g. Other ingredients - Egg Phosphatides 12g, Glycerol 22.5g, Sodium Oleate 0.3g, Sodium hydroxide, Water for Injection. **Indications**: A source of calories and essential fatty acids for patients requiring parenteral nutrition. **Dosage and Route:** Intravenous infusion as part of a parenteral nutrition regimen. **Adult Patients:** Can provide up to 60% of the energy requirements. Starting infusion rate 0.5ml per minute for the first 15-30 minutes, increase slowly to allow 500ml to be administered on the first day. Subsequently, dose may be increased to a maximum of 2.5g lipids/kg of body weight/day (maximum infusion rate 0.25g lipids/kg/hour). **Paediatric Patients:** Can provide up to 60% of the energy requirements. Starting rate 0.05ml per minute for the first 10-30 minutes. Never exceed 0.25g lipids/kg/hour. Maximum daily dosage - 4g lipids/kg of body weight. In small for gestational age or premature infants with impaired capacity to metabolise fat, initial dosage should be 0.5g lipids/kg/day increasing daily by 0.25g lipids/kg/day up to a maximum of 3g lipids/kg/day. Fat clearance must be monitored closely every day. If serum triglycerides are not monitored, maximum dosage 2g lipids/kg body weight/day. Protect solution from light exposure until completion for use in neonates and children under 2 years. **Side effects:** *See Summary of Product Characteristics for full detail.* Common – Hyperglycaemia, hypoproteinaemia, hyperlipidaemia, mean arterial pressure decreased, nausea /vomiting, abdominal distension, cholestasis, muscle spasms, blood bilirubin increased, liver function test abnormal, blood triglycerides increased. Uncommon – Leukopaenia, circulatory collapse, hypotension, dyspnoea, cytolytic hepatitis, pancreatic enzyme increased. Unknown – Hypersensitivity, thrombocytopaenia, cholecystitis, cholelithiasis. Very rare – Fat overload syndrome. **Precautions**: Stop infusion immediately if abnormal signs or symptoms of allergic reaction. Patients requiring parenteral nutrition often predisposed to infectious complications – heighten emphasis on aseptic technique and monitor signs, symptoms and laboratory tests to help recognize early infections. Caution in severe liver damage, anaemia and blood coagulation disorders. During long term parenteral nutrition, monitor liver function, blood count and coagulation parameters. Overdose and/or higher than recommended infusion rate may cause fat overload syndrome. Refeeding severely undernourished patients may result in refeeding syndrome – can be prevented by careful monitoring and slowly increasing nutrient intakes (see SmPC for patient types most at risk). Check compatibility of glucose and/or amino acid solutions before administration – formation of precipitates could result in microvascular pulmonary emboli. Monitor fluid status, particularly in patients with acute oliguria, anuria, pulmonary oedema or heart failure. Correct electrolyte equilibration disorders, severe fluid overload states and severe metabolic disorders before starting infusion. Administer fat emulsions with carbohydrates and amino acids to avoid metabolic acidosis. Parenteral Nutrition Associated Liver Diseases (PNALD) are known to develop in some patients on parenteral nutrition - patients developing abnormal laboratory parameters/other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases. There is no adequate data from the use of ClinOleic 20% in pregnant and lactating women. Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing ClinOleic 20%. Due to generation of peroxides and other degradation products, protect solution from ambient light until administration completed for use in neonates and children under 2 years. **Contraindications**: Hypersensitivity to egg, soya or peanut protein or to any of the active substances or excipients. Severe hyperlipidaemia, and severe disorders of lipid metabolism characterised by hypertriglyceridemia, lipoid nephrosis and acute pancreatitis if accompanied by hyperlipaemia. **Interactions:** Do not add medication or electrolytes directly to the lipid emulsion without verifying compatibility. Naturally contains vitamin K_1 which may counteract anticoagulant activity of coumarin derivatives. **Overdose**: In the event of fat overload during therapy, stop infusion or if necessary, continue at a reduced dosage until plasma triglyceride concentration has returned to baseline. **Legal category:** POM. **Basic NHS price:** FDB9500 100 ml £6.28, FDB9501 250 ml £10.08, FDB9503 500 ml £13.88. **Marketing Authorisation Number and Holder:** PL 00116/0313. Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE. **Date of revision:** May 2020**.**