Fatisol

Intravenous Fat Emulsion 10%

Description

Fatisol is a preparation of 10% refined soyabean oil intended to be used as an intravenous nutrient. *Fatisol prevents Essential Fatty Acid Deficiency (EFAD) and corrects the clinical manifestations of EFAD. However, for patients requiring complete parenteral nutrition, complementary vitamin supplements are required.*

Composition

Refined Soyabean Oil	BP	10 g
Purified Egg Lecithin	Ph. Gr.	1.2 g
Glycerol	BP	2.25 g

Clinical Pharmacology

Fatisol are prepared from either soyabean or safflower oil and provide a mixture of neutral triglycerides, predominantly unsaturated fatty acids. The major components of fatty acids are linoleic, oleic, palmitic acids. In addition, *Fatisol* contains 1.2% egg yolk phospholipids as an emulsifier and glycerol to adjust tonicity. IV Fat emulsions are isotonic and may be given by central or peripheral venous route. *Fatisol* is formulated as a concentrated source of energy to be used together with carbohydrates and amino acids in parenteral nutrition, it is isotonic, and provides a source of basal phosphate requirements and a source of vitamin E.

Indications

Fatisol is a source of calories and essential fatty acids for patients requiring parenteral nutrition for extended periods of time (usually for >5 days). It is a source of essential fatty acids when a deficiency occurs. Part of the intravenous diet in all parenteral nutrition indications including:

- Preoperative and postoperative nutritional disturbances where an improved nitrogen balance is required;
- Nutritional disorders or disturbances of nitrogen balance due to inadequate or failing intestinal absorption caused by tumours in the gastrointestinal tract, acute or chronic intestinal diseases (peritonitis, ulcerative colitis, terminal ileitis);
- Burns, to reduce the frequently excessive nitrogen losses; Prolonged unconsciousness, eg. following cranial trauma or poisoning in cases where enteral feeding is inappropriate or impossible;
- Impaired renal function where a concentrated source of energy may be indicated to reduce protein breakdown;
- Cachexia and Patients with essential fatty acid deficiency who cannot maintain or restore a normal essential fatty acid pattern by oral intake.

Dosage and Administration

Total Parenteral nutrition: As a part of TPN, administer IV via a peripheral vein or by central venous catheter. Fat emulsion should comprise no more than 60% of the patient's total caloric intake, with carbohydrates and amino acids comprising the remaining 40% or more of caloric intake. ***Adult:*** Initial infusion rate is 1ml/min for the first 15 to 30 mins. If no adverse reactions occur, the infusion rate can be increased to 2 ml/min. Infuse only 500 ml the first day and increase dose the following day. Do not exceed a daily dosage of 2.5 g/kg. ***Children:*** Initial infusion rate is 0.1ml/min for the first 10 to 15 mins. If no adverse reactions occur, the infusion rate can be increased to 1g/kg in 4 hours. Do not exceed a daily dosage of 3 g/kg. ***Infants:*** Starts at 0.5g/kg/24 hours and may be increased in relation to the infant's ability to eliminate fat. The maximum recommended dosage is 3g/kg/24 hours. ***Fatty acid deficiency:*** To correct EFAD, supply 8% to 10% of the caloric intake by IV fat emulsion to provide an adequate amount of linoleic acid.

The left over contents of opened bottles should be discarded & not saved for later use.Do not use any bottles in which there appears to be separation of the emulsion.

Route of Administration

Fatisol can be given by a peripheral or central vein, either alone or simultaneously with amino acid and/or glucose 10% to 30%, through a twin infusion set or separate sets connected to a single tap so that the mixture reaches the vein through the same cannula.

Adverse Effects

Fatisol IV infusion may cause a rise in body temperature (incidence <3%) and, less frequently, shivering, chills and nausea/vomiting (incidence <1%). Reports of other adverse events in conjunction with 10% fat emulsion infusion are extremely rare, less than one report of certain events per one million infusions.Hypersensitivity reactions (anaphylactic reaction, skin rash, urticaria), respiratory symptoms (tachypnoea) and circulatory effects (hypertension, hypotension) have been described. Thrombosis, haemolysis, reticulocytosis, abdominal pain, tiredness, priapism and neurological adverse reactions including headaches, flushing, dyspnoea, slight pressure over the eyes and dizziness have been reported.

Contraindications

Fatisol is contraindicated in conditions with severely disordered fat metabolism, such as in severe liver damage and acute shock. Hypersensitivity to egg-, soya- or peanut protein or to any of active substances or excipients.

Use in Pregnancy & Lactation

Absolute safety of the foetus and the nursing infant has not been established. Therefore, *Fatisol* should be administered with caution during pregnancy and lactation.

Drug Interactions

Some drugs, like insulin, may interfere with the body's lipase system. This kind of interaction seems, however, to be of only limited clinical importance. Heparin in clinical doses causes a transient increase in lipolysis in plasma, resulting in a transient decrease in triglyceride clearance due to depletion of lipoprotein lipase.

Precautions & Warnings

Fatisol contains soya oil and egg lecithin which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Fat metabolism may be disturbed in conditions such as renal insufficiency, uncompensated diabetes, pancreatitis, certain forms of liver insufficiency, metabolic disorders and sepsis. *Fatisol* should be administered with caution as a strong correlation exists between C-reactive protein and the agglutination of *Fatisol* in seriously ill patients. *Fatisol* should be given with caution to neonates and premature infants with hyperbilirubinaemia and in cases with suspected pulmonary hypertension. In low birthweight infants, the risk of lipid infusions may outweigh potential benefits due to further diminution of defences against infection. In infants, metabolism of lipids in peripheral tissues may be diminished by infection and heparin administration. In neonates receiving long term parenteral nutrition, particularly premature neonates, platelet count, liver function tests and serum triglyceride concentration should be monitored.

Overdosage

Impaired capacity to eliminate *Fatisol* may lead to fat overload syndrome as a result of overdosage. It may also occur at recommended rates of infusion in association with a sudden change in the clinical condition such as renal function impairment or infection. Fat overload syndrome is characterised by bone marrow depression, anaemia, thrombocytopenia, hepatosplenomegaly, splenomegaly, hyperlipaemia, fever, fat infiltration, focal seizures and shock. All symptoms are usually reversible if the infusion of *Fatisol* is discontinued.

Pharmaceutical Precautions

Store at 15°C to 30°C in a dry place protected from light. Keep out of reach of children. Do not use if there is evidence of excessive creaming or aggregation, if excessive free oil droplets are visible, if the bag is leaking or if the bottle is damaged, solution is frozen, discolored or contains particles. The left over contents of opened bag or bottles should be discarded & not saved for later use. *Fatisol* contains no preservatives.

Commercial Pack

Fatisol 500 ml: Available in 500 ml Polypropylene (PP) bag overrapped by a deoxygenated PP pouch.
Fatisol 500 ml: Available in 500 ml Glass Bottle.
Fatisol 250 ml: Available in 250 ml Polypropylene (PP) bag overrapped by a deoxygenated PP pouch.
Fatisol 250 ml: Available in 250 ml Glass Bottle.

Manufactured by:

POPULAR

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