

# Lipofit

Intravenous Fat Emulsion 10%

## Composition

**Lipofit 500 IV Infusion:** Each 100 mL contains

Refined Soyabean Oil	BP	10 g
Purified Egg Lecithin	Ph. Grade	1.2 g
Glycerin	USP	2.25 g

**Lipofit 250 IV Infusion:** Each 100 mL contains

Refined Soyabean Oil	BP	10 g
Purified Egg Lecithin	Ph. Grade	1.2 g
Glycerin	USP	2.25 g

## Pharmacology

Lipofit 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, Lipofit 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. Lipofit 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.

## Indication

Lipofit 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.

## Dose and administration

Lipofit 10% Pharmacy Bulk Package is not intended for direct intravenous administration.

- For intravenous infusion only through a peripheral or central Line.
- Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize and consideration of additional energy given to the patient.

Age	Nutritional requirements	
	Initial Recommended dosage	Maximum Dosage
Preterm and term infants (<1 year)	1 to 2 g/kg/day	3g/kg/day
Pediatric patients 1 to 10 years		
Pediatric patients 11 to <17 years	1 g/kg/day	2.5 g/kg/day
Adults	1 to 1.5 g/kg/day	2.5 g/kg/day

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. Do not store partially used bags for later use. Do not use filters. Do not use any bag in which there appears to be separation of the emulsion.

## Route of administration

Lipofit 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.

### **Contra-indications**

Lipofit 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.

### **Warning and precaution**

Lipofit 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. Lipofit should be administered with caution as a strong correlation exists between C-reactive protein and the agglutination of Lipofit in seriously ill patients. Lipofit 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.

### **Side effects**

Lipofit 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.

### **Use in pregnancy & lactation**

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

### **Use in children & adolescents**

Safe for in children & adolescents.

### **Drug interaction**

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.

### **Overdosage**

Impaired capacity to eliminate Lipofit 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 Lipofit is discontinued.

### **Storage**

Store at room temperature (not exceeding 25°C) . Protect from freezing (not below 4°C) and light. Emulsion which have been frozen should be discarded. Any remaining emulsion from an opened bottle must be discarded. Do not use if the emulsion is discolored. Lipofit contains no preservatives.

### **Packing**

**Lipofit 500 IV Infusion:** Each box contains 1 glass bottle of 500 mL emulsion.

**Lipofit 250 IV Infusion:** Each box contains 1 glass bottle of 250 mL emulsion.

Manufactured By

**BEACON**<sup>®</sup>

Pharmaceuticals PLC

Bhaluka, Mymensingh, Bangladesh