

READ THE LEAFLET CAREFULLY BEFORE USE.
FOR FURTHER INFORMATION, CONSULT WITH YOUR PHYSICIAN.

Lipid LCT inj. 20%

[COMPOSITION]

100ml contains

Constitution	Product	Lipid LCT inj. 20%
Purified soybean oil		20g
Purified egg phospholipids		1.2g
Glycerol		2.2g

[APPEARANCE]

Milk-white emulsion contained in plastic fluid bag

[INDICATIONS]

Supply of calories and essential fatty acids for patients requiring parenteral nutrition.

[DOSAGE AND ADMINISTRATION]

- Adult : Generally, less than 2g/kg daily as purified soybean oil is administered by drip infusion, corresponding to 10ml/kg of Lipid LCT inj. 20%. Should be infused over at least 3 hrs. Administer less than 1g/kg as purified soybean oil at the first time.
- Perform administration according to required essential fatty acid and calories, considering physiological metabolism of the Patient.

[PRECAUTIONS]

1. Contraindications

- 1) Thrombosis
- 2) Severe liver insufficiency
- 3) Severe blood coagulation disorders
- 4) Hyperlipemia
- 5) Diabetes with ketoacidosis
- 6) Acute shock
- 7) Uncorrected electrolyte imbalance
- 8) Unstable metabolism
- 9) Hemophagocytotic syndrome
- 10) Patient with history of an allergy to phospholipid

2. Carefully administer to the following patients

- 1) Impaired liver function
- 2) Blood coagulation disorders
- 3) Respiratory disorders
- 4) Immature infants
- 5) Severe bacterial septicemia
- 6) Pregnant woman
- 7) Brain diseases
- 8) Acute pancreatitis
- 9) Coma
- 10) Impaired lipid metabolism [renal insufficiency, diabetes, pancreatitis, impaired liver function, hypothyroidism (if there is hypertriglyceridemia), and sepsis, etc.]

3. Adverse effects

- 1) Sometimes phlebitis, injection pain, bleeding tendency, recurrent phlebemphraxis, or reticulocytosis may occur.
- 2) If a hypersensitive reaction occur, the infusion must be stopped.

- 3) Hepatic disorder may occur when using continuously. In this case, adequate treatment is recommended, such as dose reduction, etc.
- 4) Sometimes blood pressure lowering, tachycardia, tachypnea, repeated dyspnea, or cyanosis may occur. If such symptoms occur at the beginning of the infusion, discontinue the infusion and treat properly.
- 5) Sometimes nausea, vomiting, diarrhea, or thirst may occur.
- 6) Sometimes pyrexia, chilliness, flushing, facial swelling, chest tightness, or priapism (when used for long time) may occur.
- 7) Overdose may cause adiposis due to abnormality of lipid metabolism. This may result to hyperlipemia, pyrexia, lipophagy, abnormality of various internal organs, delay of blood coagulation, thrombocytopenia, or even comatose state. These symptom disappear if the infusion is stopped.

4. General cautions

Liver function test, blood lipid level, blood features and blood coagulation test should be taken regularly when using continuously.

5. Drug interactions

- 1) The effect of warfarin may be reduced by fat emulsion.
- 2) Heparin given in clinical doses causes a transient release of lipoprotein lipase into the circulation, which may increase the plasma lipolysis accompanied by transient decrease of triglyceride clearance rate at initial administration

6. Use in children

- 1) Neonates, particularly very low-birth-weight neonates, and neonates with dyspnea or acidosis
 - (1) As the ability to eliminate lipids is not fully developed yet in preterm infants and low-birth-weight neonates, should be administered carefully to consider the following conditions.
 - (2) Administer as slowly as possible. Infusion rate should not exceed 0.08g of fat/kg/hour.
 - (3) In case of infant who is deemed as having very low ability to eliminate lipid, it is better to monitor blood lipids level and infuse at a rate that avoids a radical increase of it.
- 2) In neonates with dyspnea, especially in very low-birth-weight neonates, as there's a report that fat emulsion exacerbates it, close monitoring is recommended.
- 3) In case of the administration to children or premature infants with hyperbilirubinemia or suspicious pulmonary hypertension, platelets, liver enzyme level, serum triglyceride and fatty acids level should be monitored.
- 4) In case of neonates with suspicious sepsis or increasing C-reactive protein level, serum triglyceride level should be monitored carefully.
- 5) The long term administration may cause thrombocytopenia in children.

7. Use in aged people

As aged people generally shows reduced physiologic functions, should be administered carefully.

8. Influence on laboratory measurements

When the blood is collected prior to the entire elimination of lipid from blood, lipid ingredients may interfere with certain laboratory measurements (such as bilirubin, lactate dehydrogenase, oxygen saturation, hemoglobin, etc.). In most patients, the blood is cleared of fat after an interval of 5-6 hours.

9. Precautions to use

- 1) Use only as an intravenous infusion.
- 2) The too rapid infusion of fat emulsion can cause acute symptoms of phlebitis, injection pain, tachycardia, rapid respiration, nausea, vomiting, pyrexia, chilliness, flushing, and chest tightness. So observe the following precautions.
 - (1) Administer slowly.
 - (2) Do not mix with other medications, and do not administer until 96 hours after injecting blood volume expander (dextran, gelatin, etc.).
- 3) Phlebitis or injection pain may occur sometimes when the temperature of the solution is too low.
- 4) Once a needle is inserted into the stopper, use immediately and discard any remaining solution properly.
- 5) Do not use this product if it has been frozen.

[**PACKING UNIT**] Lipid LCT inj. 20% 250ml x 20

[**SHELF LIFE**] 2years

[**STORAGE**] Store at room temperature below 25°C. Do not freeze.

※ Do not use if an oxygen indicator (orange tablet) was discolored to dark purple due to risk of oxygen permeation.