Otsuka Otsuka Pharmaceutical India Private Limited

Artwork Code : 2450000460	**Artwork Req. No: 5355**
Quality of Paper/Board : Super Sun Shine	**Size of Artwork (In mm) : 210x133**
Quality of Gum :	**GSM of Paper/Board : 60 GSM**

Colour Code : BLACK ■ | Pantone ☐ | Pantone ☐ | Pantone ☐ | Pantone ☐ | Pantone ☐ | Pantone ☐ | Pantone ☐

Barcode Information:
Barcode Scan Report:

Packing: 250ml GLB	**Plant Location : MF 02**
Country: Malaysia	**Language : English**
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For the use of a Registered Medical Practitioner, Hospital or a Laboratory only.

CELEPID 10% & 20%

Intravenous Fat Emulsion

DESCRIPTION

CELEPID is a stable fat emulsion prepared from Soybean Oil, Egg Lecithin, Glycerol and Water for Injection. Fat emulsions have the advantage of having high caloric yield. They are also isotonic with blood and hence can be infused peripherally.

The Soybean Oil of ***CELEPID*** provides essential fatty acids which help avoid essential fatty acid deficiency, its associated biochemical changes and clinical manifestations like scaly skin, growth retardation, sparse hair growth & delayed wound healing. A parenteral feeding regimen which contains Carbohydrates, Amino acids and Fats provides a balanced metabolic load. Thus fat emulsions are indispensable unless fats are contraindicated.

COMPOSITION

CELEPID is an intravenous fat emulsion and has the following composition.

Each 100 ml (of emulsion) contains :

	CELEPID 20%	***CELEPID*** 10%
Soybean Oil USP	20.00 g	10.00 g
Egg Lecithin	1.20 g	1.20 g
Glycerol USP	2.25 g	2.25 g
Water for Injections BP	q.s.	q.s.
Energy Content	2000 kcal/L	1100 kcal/L
Osmolarity	279 mOsmol/L	300 mOsmol/L

PHARMACOLOGY

CELEPID is a concentrated energy source for complete intravenous nutrition. Provision of a sufficient amount of energy in the form of carbohydrate is often restricted by such considerations as hypertonicity, hypervolaemia, tendency to thrombophlebitis and the limit beyond which further carbohydrate cannot be utilised. By the use of ***CELEPID*** it is possible to provide a high energy intake in a relatively small volume.

CELEPID is a rich source of the essential fatty acids, linoleic and linolenic acids. It has a protein sparing effect when given in conjunction with amino acid and carbohydrate solutions.

The pharmacodynamics effects of ***CELEPID*** are limited due to the nature of the product.

CELEPID is intended to be a substitute for the naturally occurring chylomicrons which enter the blood stream after gastrointestinal absorption of fat.

CELEPID is metabolised in a similar way to chylomicrons.

INDICATIONS

CELEPID should be used to supply energy and essential fatty acids to patients needing intravenous nutrition. ***CELEPID*** is also indicated for patients with essential fatty acid deficiency who can not maintain or restore a normal essential fatty acid pattern by oral intake.

CONTRAINDICATIONS

CELEPID is contra-indicated in severe disorders of fat metabolism such as in severe liver damage and acute shock.

Warnings and Precautions

CELEPID should be given with caution in conditions of impaired lipid metabolism such as renal insufficiency, uncompensated diabetes mellitus, pancreatitis, certain forms of liver insufficiency, hypothyroidism (if hypertriglyceridemic), metabolic disorders and sepsis. Fat membolism has been reported in a few cases when the recommended infusion rate has been exceeded in these patients.

If intravenous administration of fat is considered in patients with the above mentioned disorders, the elimination of fat should be checked daily. Patients known to be allergic to soy protein, should be given ***CELEPID*** with caution and only after hypersensitivity tests.

In new-borns with neonatal hyperbilirubinaemia ***CELEPID*** should be used with caution, especially in low birth-weight infants, because of the risk of free fatty acids displacing bilirubin from albumin. ***CELEPID*** should be administered with caution to infants with known or suspected pulmonary hypertension. In neonates, particularly prematures on long term parenteral nutrition, platelet count, liver test and serum triglyceride concentration should be monitored.

CELEPID may interfere with certain laboratory measurements (bilirubin, lactate dehydrogenase, oxygen saturation, Hb etc) if blood is sampled before fat is adequately cleared from the blood stream. Fat is cleared after a fat free interval of 4 to 6 hours in most patients.

Fat Elimination:

The ability to eliminate fat should be closely monitored in patients with conditions mentioned under Special Warnings (this section), but also in patients given ***CELEPID*** for more than one week. This is done by collecting a blood sample after a fat-free clearance period of 4-6 hours.

Blood cells are then separated from plasma by centrifugation (1200-1500 rotations per minute, rpm). If the plasma is opalescent, the infusion should be postponed. The sensitivity of the method is such that hypertriglyceridaemia can pass undetected. Therefore, it is recommended that serum triglyceride concentrations are measured in patients who are likely to have an impaired fat tolerance.

CAUTION

After the infusion is initiated, the patient is closely observed for signs of acute hypersensitivity characterized by chills, palpitation, dyspnea. These reactions may be associated with a faster flow rate and this occurrence necessitates a reduction in flow rate.

- Do not store partially used bottles.
- Do not use the fluid if any separation of phases of the emulsion is visible.
- Emulsion should not be mixed with electrolytes or other additives.

Poor maternal weight gain increases the risk of delivery of a low birth weight infant, thus increasing the risk of neonatal death. Fat emulsion may be useful for preventing such nutritional deficits. Successful and safe administration of lipid emulsion in pregnant women has been reported.

Pregnancy and Lactation

Animal reproduction studies have not been carried out with ***CELEPID***. There are, however, published reports of its successful and safe administration during pregnancy in the human.

Interactions with Other Medicaments

Some drugs, like insulin, may interfere with the body's lipase system.

However, this kind of interaction seems 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 due to depletion of lipoprotein lipase.

Soybean oil has a natural content of vitamin K1. This is considered important only for patients treated with coumarin derivatives, which interfere with Vitamin K1.

ADVERSE REACTIONS

In rare instances, initial administration of ***CELEPID*** has produced a rise in temperature and less frequently, shivering, chills and nausea / vomiting (incidence < 1%). Infusion of ***CELEPID*** should be discontinued in such cases. Other adverse event reports are extremely rare, occurring in less than one in one million infusions.

The following have been reported occurring immediately or soon after commencing infusion:

Hypersensitivity reactions (anaphylaxis, skin rash, urticaria), respiratory symptoms (eg. tachypnoea), circulatory effects (eg. hyper/hypotension),

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haemolysis, reticulocytosis, abdominal pain, headache, tiredness and priapism.
Increased levels of transaminases, alkaline phosphatase and bilirubin have been observed in patients receiving intravenous nutrition, with or without ***CELEPID***. If the dosage is reduced values usually return to normal. Cholestasis has also been reported.
Thrombocytopenia has been reported in association with prolonged treatment with ***CELEPID*** in infants.

DOSAGE
The dosage and infusion rate should be within the ranges recommended below and should be governed by the patient's ability to utilise fat.
Recommended dosage for adults:
CELEPID 20%: 500-1000 ml per 24 hours in conjunction with intravenous administration of amino acid and carbohydrate solutions. For lesser energy requirements ***CELEPID*** 10% 500-1500 ml per 24 hours in conjunction with amino acid and carbohydrate solutions.
Essential fatty acid deficiency:
When ***CELEPID*** is administered to prevent or correct essential fatty acid deficiency, 4-8% of non protein calories should be supplied as ***CELEPID*** to provide sufficient amounts of linoleic and linolenic acids.
When EFAD is associated with stress, the amount of ***CELEPID*** needed to correct the deficiency may be substantially increased.
Recommended dosage for infants:
Dosage is governed by the maturity and birth-weight of the infant. In mature infants dosage scheme I should be used. In small for gestational age and low birth-weight infants where the ability to handle fat may be impaired, dosage scheme 2 should be utilised.
In all cases, the infant's ability to eliminate infused fat from the circulation should be checked daily. Measuring serum triglycerides is the only reliable method. If lipaemia is present retesting should be carried out after an interval of four hours.
When administered to infants ***CELEPID*** should, if possible, be infused continuously over 24 hours and to maintain a constant rate of infusion it is essential that an appropriate pump is used.
1) ***Infants:*** 0.5-4 g fat per kg body weight in 24 hours. In practice 0.02-0.17g/kg body weight should be administered each hour. The equivalent volumes of ***CELEPID*** are 10% 0.21-1.70 ml/kg/hour; 20% 0.10-0.85 ml/kg/hour. The dosage should be gradually increased during the first week of administration.
2) ***To premature and low birth weight infants:*** CELEPID should be administered continuously during 24 hours/day. The initial infusion rate should be 0.5 - 1.0 g/kg/24 hours (2.5 - 5.0 ml ***CELEPID*** 20%/kg/24 hours). The dose is then increased by the same amount (0.5 - 1.0 g/kg) every 24 hour period up to 2.0 g/kg/24 hours (10 ml ***CELEPID*** 20%/kg/24 hours). The dose can only be increased above that level and up to a maximum of 4.0 g/kg/24 hours (20 ml ***CELEPID*** 20%/kg/24 hours) by concomitant careful monitoring by following the triglyceride levels, liver function tests and oxygen saturation.
The rates given are maximum rates and no attempt should be made to exceed these in order to compensate for missed doses.
Recommended dosage for the elderly:
Age per se requires no adjustment of the adult dosage. However, caution should be exercised in the "frail" elderly and indeed in all patients with poor renal, cardiac or liver function, where smaller volumes should be used depending on the individual's requirements and condition.

Administration:
CELEPID 10% and 20% are administered by slow intravenous infusion. During the first 10 minutes the drip should be adjusted to 20 drops per minute and then gradually increased to a final rate after half an hour of 25-40 drops per minute for ***CELEPID*** 20% and 40-60 drops per minute for ***CELEPID*** 10%. 500 ml of ***CELEPID*** 20% should be given over a period of not less than five hours. 500 ml of ***CELEPID*** 10% should be given over a period not less than three hours. On the first day of infusion it is advisable to administer 5 ml ***CELEPID*** 20% per kg body weight or 10 ml ***CELEPID*** 10% per kg body weight. Subsequently the dose is usually doubled and when a larger intake is indicated the dosage may be increased to a maximum of 3 g fat per kg body weight per 24 hours.
CELEPID may be given as a separate infusion or as an admixture. When separate infusion is preferred the fat emulsion may be infused into the same central or peripheral vein as carbohydrates/amino acid solutions by means of a Y-connector near the infusion site.
CELEPID can also be given as part of an All in One admixture containing carbohydrates, amino acids, electrolytes, vitamins and trace elements. The admixture must be approved for physical stability.
As with all infusions, care should be taken to avoid complications of catheterisation including air embolism and central venous thrombosis. The risk of serious thoracic complications can be avoided by the use of a peripheral catheter. The provision of intravenous nutrition via a peripheral catheter is facilitated by the near isotonicity of ***CELEPID***. Strict asepsis should be maintained, especially in the immunosuppressed patient.
Monitoring:
Electrolyte, fluid, acid-base imbalance and shock should be corrected prior to commencement of intravenous nutrition. In the metabolic and nutritional management of the seriously ill patient, specific preliminary investigations and continuous monitoring are essential, particularly of electrolyte levels. Monitoring of vitamin and trace element levels should be included, especially in patients receiving long-term intravenous nutrition.

ADMINISTRATION
CELEPID is available as a sterile, non-pyrogenic, single dose container that can be administered through peripheral veins or by central venous route using non-pyrogenic I.V. administration set with aseptic technique.

OVER DOSAGE
If a fat overload occurs during therapy, the fat infusion must be stopped immediately. Further therapy should be initiated with appropriate corrective measures.

STORAGE
Store below 30°C. Do not freeze.

PRESENTATION
CELEPID 20% is available in 250 ml & 500 ml glass bottles.
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MAL No. for Celepid 10% : MAL14055022X
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Date of Revision: 10th May 2019
Product Registration Holder,
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2450000460