Baxter

Clinolipid

20% (LIPID INJECTABLE EMULSION)
FOR INTRAVENOUS USE

Introducing **Clinolipid 20%** (Lipid Injectable Emulsion) for intravenous use into your Parenteral Nutrition (PN) program

CLINOLIPID injection is indicated in adults for providing a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.[1]

Limitations of Use

CLINOLIPID injection is not indicated for use in pediatric patients because there is insufficient data to demonstrate that CLINOLIPID injection provides sufficient amounts of essential fatty acids in this population.

The omega-3: omega-6 fatty acid ratio in CLINOLIPID injection has not been shown to improve clinical outcomes compared to other intravenous lipid emulsions.

When admixing CLINOLIPID, protect the admixed parenteral nutrition solution from light.

Use only a 1.2 micron in-line filter during administration of CLINOLIPID alone and or as part of an admixture.

In an effort to support your PN program and address any concerns related to admixture stability, Baxter has studied the physical compatibility of Clinolipid when admixed as a total nutrient admixture with Amino Acid (AA) injections, dextrose, electrolytes and micronutrients. Formulas were tested to represent a matrix of high and low end concentrations as outlined in the table below. Trace elements and multivitamins were added after the refrigeration period prior to room temperature storage. All admixtures were evaluated for physical compatibility after storage for 9 days refrigerated (2-8° C) plus an additional storage of 48 hours at room temperature (25° C ± 2° C).[1]

		CLINOLIPID Admixture Stability Parameters with Amino Acids		
	Ingredient	10% TRAVASOL (amino acids) injection, for intravenous use	15% CLINISOL sulfite free (Amino Acid) injection	20% PROSOL (amino acids) injection, for intravenous use
Macro-nutrients	Amino Acids	22g/L - 45g/L	25g/L - 68g/L	30 g/L - 60 g/L
	Dextrose	50g/L - 181g/L	50g/L - 181g/L	150 g/L - 250 g/L
	CLINOLIPID	20g/L - 36g/L	20g/L - 36g/L	10 g/L - 50 g/L
Electrolytes	Sodium	150 mEq/L	150 mEq/L	78 mEq/L
	Potassium	75 mEq/L	75 mEq/L	40 mEq/L
	Magnesium	11 mEq/L	11 mEq/L	5 mEq/L
	Calcium	10 mEq/L	10 mEq/L	7 mEq/L
	Phosphate	8 mMol/L	8 mMol/L	11 mMol/L
	Chloride[a]	159 - 169 mEq/L	150 mEq/L	64 mEq/L
	Acetate[b]	82 - 103 mEq/L	85 - 121 mEq/L	61 - 82 mEq/L
Vitamins & Trace Elements (TE)	Adult TE Concentrate[c]	1 mL	1 mL	1 mL
	Multivitamin - Adult[c]	10 mL	10 mL	10 mL

[a] Chloride contributions inherent from AA Ingredient and Sodium Chloride [b] Acetate contribution inherent from AA Ingredient
[c] Vitamins and trace elements were added at 1 daily dose/L

Only the physical compatibility of the 3-in-1 CLINOLIPID admixtures was evaluated, the chemical stability or bioavailability of each ingredient was not tested. Admixture stability was tested by visual inspection, pH, mean lipid droplet diameter (consistent with USP<729> Method I) and microscopic particle count test (consistent with USP<788>). This information is provided as a guide and not intended to replace good clinical judgment.

CONCLUSION: All formulations tested within the ranges indicated in the table above were physically stable at the maximum storage period of 9 days refrigerated followed by 48 hours at room temperature (25° C ± 2° C).

See page 2 for Clinolpid Indication and Important Risk Information. Click here for Full Prescribing Information for Clinolipid.

Click here for Full Prescribing Information for Travasol, Clinisol, and Prosol.

Two concentrations of dextrose 70% and CLINOLIPID 20% injection were mixed with one of three amino acid formulations (TRAVASOL 10%, CLINISOL 15%, PROSOL 20%). After mixing, the final concentration of CLINOLIPID ranged from 1% to 5%, the amino acid concentration ranged from 2.2% to 6.8% and the dextrose concentration ranged from 5% to 25%. Commonly used electrolytes (sodium, potassium, magnesium, calcium and phosphate), trace elements and a multivitamin preparation were included in the base total nutrient admixture formulations.

CLINOLIPID 20% (Lipid Injectable Emulsion) for intravenous use

Indication

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Limitations of Use

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Important Risk Information

- The use of CLINOLIPID injection is contraindicated in patients with the following:
  - Known hypersensitivity to egg, soybean, peanut or any of the active or inactive ingredients.
  - Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglycerides >1,000 mg/dL).
- Clinical Decompensation with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported.
- Parenteral Nutrition-Associated Liver Disease (PNALD): Increased risk in patients who receive parenteral nutrition for greater than 2 weeks, especially preterm neonates. Monitor liver tests; if abnormalities occur, consider discontinuation or dosage reduction.
- Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reactions occur.
- Risk of Infections, Fat Overload Syndrome, Refeeding Syndrome, Hypertriglyceridemia, and Essential Fatty Acid Deficiency (EFAD): Monitor for signs and symptoms; monitor laboratory parameters.
  - Ensure aseptic techniques are used for catheter placement, catheter maintenance, and preparation and administration of CLINOLIPID.
  - If signs or symptoms of fat overload syndrome occur, stop CLINOLIPID.
  - To prevent complications from Refeeding Syndrome, closely monitor severely malnourished patients and slowly increase their nutrient intake.
  - Measure serum triglycerides before the start of infusion and regularly throughout treatment. If triglyceride levels are above 400 mg/dL in adults, stop the CLINOLIPID infusion and monitor serum triglyceride levels to avoid clinical consequences of hypertriglyceridemia.
- Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm neonates. CLINOLIPID injection contains no more than 25 mcg/L of aluminum.
- Frequent clinical and laboratory determinations are necessary throughout treatment. Monitor fluid status closely in patients with pulmonary edema or heart failure.
- Content of Vitamin K may counteract anticoagulant activity coumarin derivatives, including warfarin.
- The most common (5%) adverse drug reactions reported from clinical trials were nausea and vomiting, hyperlipidemia, hyperglycemia, hypoproteinemia and abnormal liver function tests.
- For infusion into a central or peripheral vein. When administered with dextrose and amino acids, choice of central or peripheral venous route is dependent on the osmolarity of the final infusate.
- When admixing CLINOLIPID, protect the admixed parenteral nutrition solution from light.
- Use only a 1.2 micron in-line filter during administration of CLINOLIPID alone and or as part of an admixture.
- CLINOLIPID 1,000mL Pharmacy Bulk Package is only indicated for use in pharmacy admixture programs for the preparation of three-in-one or total nutrition admixtures.

Click here for Full Prescribing Information for Clinolipid.

1. Internal data on file.

For additional information please contact your local Baxter Nutrition Specialist or email medinfo@baxter.com.

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