Baxter

Clinolipid

(LIPID INJECTABLE EMULSION), FOR INTRAVENOUS USE

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

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

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

When admixing CLINOLIPID in the pharmacy, prepare the admixture using strict aseptic techniques to avoid microbial contamination. Do not add additives directly to CLINOLIPID. If CLINOLIPID is mixed with dextrose and/or amino acid solutions, check the compatibility before administration by inspecting the mixture closely for the presence of precipitates. Formation of precipitates could result in vascular occlusion. Do not use administration sets and lines that contain di 2-ethylhexyl phthalate (DEHP) and use a 1.2 micron pore size in-line filter for the administration of CLINOLIPID and or admixtures prepared with CLINOLIPID.

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 TNA 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	21.8 g/L - 45.3 g/L	25.3 g/L - 68.1 g/L	30 g/L- 60 g/L
	Dextrose	50.4 g/L - 181.3 g/L	50 g/L - 180.8 g/L	150 g/L – 250 g/L
	CLINOLIPID	20 g/L - 36.2 g/L	20 g/L - 36.1 g/L	10 g/L- 50 g/L
Electrolytes	Sodium	up to 150 mEq/L	up to 150 mEq/L	up to 78 mEq/L
	Potassium	up to 75 mEq/L	up to 75 mEq/L	up to 40 mEq/L
	Magnesium	up to 11.2 mEq/L	up to 11.2 mEq/L	up to 5.3 mEq/L
	Calcium	up to 10 mEq/L	up to 10 mEq/L	up to 7.4 mEq/L
	Phosphate	up to 8 mMol/L	up to 8 mMol/L	up to 10.5 mMol/L
	Chloride[a]	up to 168.1 mEq/L	up to 150 mEq/L	up to 64 mEq/L
	Acetate[b]	Variable	Variable	Variable
Vitamins & Trace Elements (TE)	Adult TE Concentrate[c]	1 mL	1 mL	1 mL
	Multivitamin - Adult[c]	10 mL	10 mL	10 mL

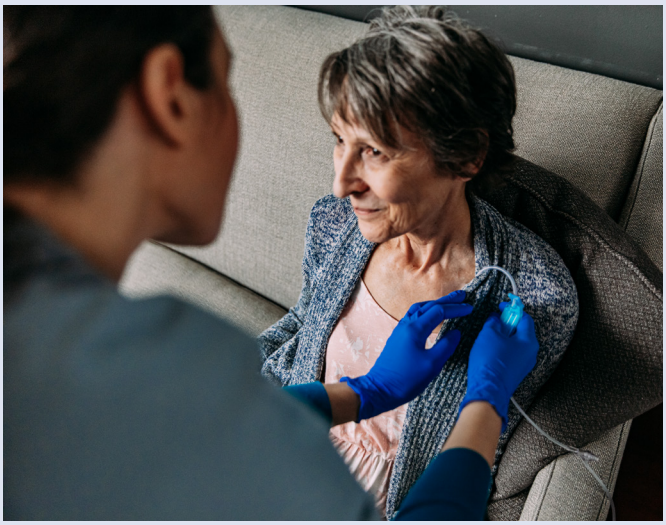
[a] Chloride contributions inherent from AA Ingredient and Sodium Chloride [b] Acetate contribution inherent from AA Ingredient
[c] Vitamins and trace elements were added at 1 daily dose/L

Only the physical compatibility of the 3-in-1 CLINOLIPID admixtures was evaluated, the chemical stability or bioavailability of each ingredient was not tested. 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 up to the maximum storage period of 9 days refrigerated followed by 48 hours at room temperature (25° C ± 2° C).

Please see reverse side for Indications, Important Risk Information including Boxed Warning for Clinolipid and pocket for full Prescribing Information. Travasol, Clinisol and Prosol full Prescribing Information can be found in pocket.

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 TNA formulations.



CLINOLIPID 20% (Lipid Injectable Emulsion) for intravenous use

Indication

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.

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.

Important Risk Information

WARNING: DEATH IN PRETERM INFANTS

- **Deaths in preterm infants after infusion of intravenous lipid emulsions have been reported in the medical literature.**
- **Autopsy findings included intravascular fat accumulation in the lungs.**
- **Preterm and low birth weight infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion.**

- The use of CLINOLIPID injection is contraindicated in patients with the following:
  - Known hypersensitivity to egg or soybean proteins, the lipid emulsion and/or excipients.
  - Severe hyperlipidemia or severe disorders of lipid metabolism.
- Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity or allergic reaction develop.
- Monitor for signs and symptoms of fat overload, essential fatty acid deficiency (EFAD) and infections including laboratory test results (including leukocytosis and hyperglycemia) and frequent checks of the parenteral access device.
- Carefully monitor severely undernourished patients and slowly increase their nutrient intakes, while avoiding overfeeding, to prevent refeeding complications.
- 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.
- CLINOLIPID injection contains no more than 25 mcg/L of aluminum. There is an increased aluminum toxicity risk in patients with impaired kidney function, including preterm infants.
- Parenteral Nutrition Associated Liver Disease (PNALD) has been reported in patients who receive parenteral nutrition for extended periods of time, especially preterm infants. Monitor liver function tests. If patients develop liver test abnormalities consider discontinuation or dose reduction.
- Reduce dose of CLINOLIPID injection and monitor serum triglyceride levels in patients with serum triglyceride concentrations above 400 mg/dL.
- The most common (5%) adverse drug reactions reported during CLINOLIPID injection clinical trials were nausea and vomiting, hyperlipidemia, hyperglycemia, hypoproteinemia and abnormal liver function tests.

Please see pocket for the full Prescribing Information including Boxed Warning.

1. Internal data on file.

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

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USMP/CLN/19-0047(1) 1/2020

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