Baxter

Clinimix
AMINO ACID IN DEXTROSE INJECTION

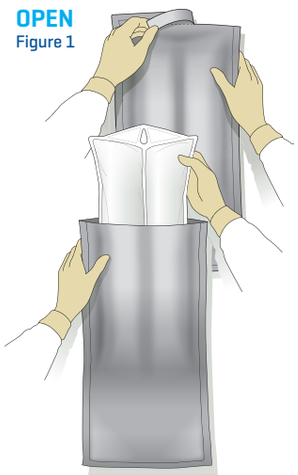
Clinimix E
AMINO ACIDS WITH ELECTROLYTES IN DEXTROSE WITH CALCIUM INJECTION

Now available with **HIGHER PROTEIN [AMINO ACID]**

How to Use **Clinimix** and **Clinimix E** Injections

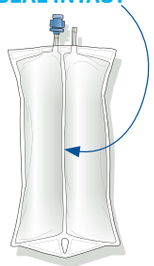
#1 BAG ACTIVATION (**Clinimix** and **Clinimix E** Injections with **2 and 3 ports**)

OPEN
Figure 1



- Tear overwrap across top slit (Figure 1) and remove the container from the overwrap.

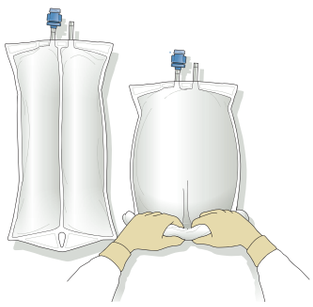
VERIFY SEAL INTACT
Figure 2



- Check to ensure seal is intact between the two chambers; discard if the seal has been activated inadvertently or if there are any leaks (Figure 2).

NOTE: Some opacity of the plastic may be observed; this is due to moisture absorption during the sterilization process. This is normal and does not affect the solution quality or safety.

ACTIVATE
Figure 3



- The container should be at room temperature. To proceed with activation, place the room temperature bag flat on a table with the label facing you. The top of the bag (hanger end) should be nearest you with the ports pointing away from you. Grasp the bag on each side of the top of the bag. Using some pressure, slowly roll the bag to open the seal between the chambers (Figure 3). Be sure the contents of both chambers are mixed together after breaking the peel seal. Do not pull or rip the seal apart.

MIX
Figure 4

- Mix solutions thoroughly by turning the container upside down at least 3 times; discard if there are any leaks (Figure 4).

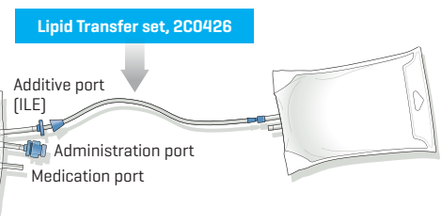
#2 ADDITIVES (After Bag Activation)

Large volume additives should be transferred prior to small volume additives.

Clinimix and **Clinimix E** Injections are available in a three port container configuration and a two port container configuration.

Figure 5

3 PORT

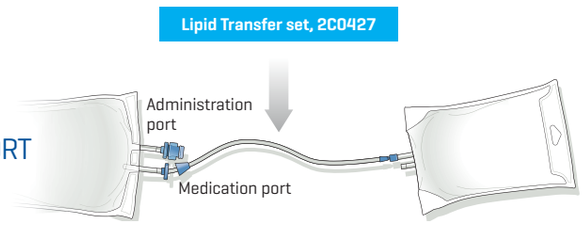


The **three port configuration** (figure 5) consist of one medication port, one additive port and one administration port. Using aseptic technique, additives can be introduced to the container through the medication port and lipids through the additive port.

When completing large volume transfers, use appropriate clamp and hand sealer to seal off additive port tube before removing the transfer set.

Figure 6

2 PORT



In the **two port configuration** (figure 6), the ports consist of one medication port and one administration port. Using aseptic technique, additives, including lipids, can be introduced to the container through the medication port.

To add medications for both 2 and 3 port containers: Prepare medication port; puncture using a 19–22 gauge needle. Inject additives; mix thoroughly and check for leaks.

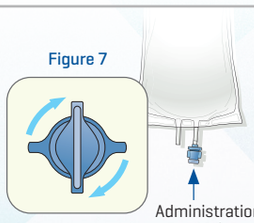
Other Additives as required may include vitamins, additional electrolytes, trace elements.

WARNING: Additives may be incompatible, please consult with your pharmacist. Questions about compatibility may be directed to Baxter.

#3 ADMINISTRATION

- Hang bag.
- Remove twist-off protector from Administration Port (Figure 7).
- Attach administration set.

Figure 7



STABILITY

- The product is good through the expiration date stated on the top of the container.
- Once removed from overwrap, the product can be stored under refrigeration for up to 9 days activated or inactivated — WITHOUT additives.
- Admixtures containing additives should be used promptly. Any storage should be under refrigeration and limited to less than 24 hours.

Please see pocket for Indications and Important Risk Information. Please see accompanying Package Inserts for full Prescribing Information.

Indications

CLINIMIX (amino acids in dextrose) Injections and CLINIMIX E (amino acids with electrolytes in dextrose with calcium) Injections are indicated as a source of calories and protein (and electrolytes for CLINIMIX E) for patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. CLINIMIX and CLINIMIX E may be used to treat negative nitrogen balance in patients.

Important Risk Information

- CLINIMIX and CLINIMIX E Injections are contraindicated in patients with known hypersensitivity to one or more amino acids or dextrose; in patients with inborn errors of amino acid metabolism due to risk of severe metabolic and neurologic complications; and in patients with pulmonary edema or acidosis due to low cardiac output. In addition, CLINIMIX E is contraindicated in neonates (less than 28 days of age) receiving concomitant treatment with ceftriaxone, even if separate infusion lines are used, due to the risk of fatal ceftriaxone calcium salt precipitation in the neonate's bloodstream.
- Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. The solution should be inspected for precipitates before admixing, after admixing, and again before administration. If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation.
- Precipitation of ceftriaxone-calcium can occur when ceftriaxone is mixed with CLINIMIX E, in the same intravenous administration line. Do not administer ceftriaxone simultaneously with CLINIMIX E via a Y-site.
- Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity reaction develop.
- Monitor for signs and symptoms of early infections.
- Refeeding severely undernourished patients may result in refeeding syndrome. Thiamine deficiency and fluid retention may also develop. Monitor severely undernourished patients and slowly increase nutrient intakes.
- CLINIMIX and CLINIMIX E solutions containing more than 5% dextrose have an osmolarity of ≥ 900 mOsm/L and must be infused through a central catheter.
- CLINIMIX and CLINIMIX E contain no more than 25 mcg/L of aluminum which may reach toxic levels with prolonged administration in patients with renal impairment. Preterm infants are at greater risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions which contain aluminum. Patients with renal impairment, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.
- Parenteral Nutrition Associated Liver Disease (PNALD) has been reported in patients who receive parenteral nutrition for extended periods of time, especially preterm infants. If CLINIMIX and CLINIMIX E treated patients develop liver test abnormalities consider discontinuation or dosage reduction.
- Use CLINIMIX and CLINIMIX E with caution in patients with cardiac insufficiency or renal impairment due to increased risk of electrolyte and fluid volume imbalance.
- Monitor renal and liver function parameters, ammonia levels, fluid and electrolyte status, serum osmolarity, blood glucose, blood count and coagulation parameters throughout treatment. In situations of severely elevated electrolyte levels, stop CLINIMIX and CLINIMIX E until levels have been corrected.
- Adverse reactions include diuresis, extravasation, glycosuria, hyperglycemia, and hyperosmolar coma.

For more information, please contact Medical Information at 1-800-933-0303.

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