THE PARENTERAL NUTRITION PORTFOLIO
From Your Global Leader in PN Solutions

GIVING YOU THE POWER TO

CHOOSE

ORDERING
STERILE COMPOUNDING
MANUFACTURER-PREPARED
PHARMACY WORKFLOW
SOLUTIONS AND PREMIX
MANAGER

www.baxter.com
Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, IL 60073
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USMP/78/14-0030(1)     3K     09/15

For all drugs mentioned herein please refer to the manufacturer’s package insert for full Prescribing Information.
THE POWER TO CHOOSE IS YOURS

The accuracy of pharmacy technology, along with the ready-to-use considerations of pre-mixed solutions and the convenience of a broad portfolio, allows you to practice your way.

ORDERING

Automate and optimize sterile compounding or premix nutrition with ABACUS Software.

- Hard and soft limits help prevent ordering errors.
- Customizable order templates support your prescribing practices.

MANUFACTURER-PREPARED SOLUTIONS AND PRE-MIX

Start with Baxter IV products, manufactured to meet cGMP requirements: dextrose, amino acids, vitamins, IV fat emulsions, sterile water, and premix nutrition.

STERILE COMPOUNDING

The EXACTAMIX Compounder produces a 3-liter bag in approximately 4.5 minutes.

- Use for your compounding needs: parenteral nutrition, CRRT, cardioplegia, base solutions and epidurals.

PHARMACY WORKFLOW MANAGER

The DoseEdge TPN system helps identify compounding errors.

- Enables remote pharmacist verification from web-enabled devices on the hospital’s network.

The nutritional needs of your patients are not all the same. You need the flexibility to customize a PN regimen to meet the specific needs of your patients. Striking the correct balance of nutritional content is an important part of a patient’s recovery.
Customize. Standardize. Or Both.

Nobody gives you more PN therapy options than Baxter.
CHOOSE THE RIGHT SOFTWARE

Order information you can trust. ABACUS Calculation Software helps simplify the ordering, calculation and labeling process for compounded and premix products. It was designed to be flexible to help meet your institution’s needs and safety standards.

Precise
- Automated calculations help to minimize the risk of mistakes during the formulation ordering process
- System and facility defined warning limits indicate dosing that falls outside the warning limits
- Establish warning limits per patient type

Efficient
- Auto archive performed daily
- Automatically calculates energy, ion and salt-based ingredient volumes needed

Flexible
- Ability to create multiple order templates to facilitate multiple referral sources (Home Infusion)
- Addition of Premix parenteral nutrition to Formulary
- Customized templates support your prescribing practices

Drug information and its clinical applications are constantly evolving as research and user experiences are evaluated. Decisions regarding drug therapy must be based on the professional judgment and independent interpretation of the clinician.
ABACUS Calculation Software is intended as an adjunct to and tool for pharmacy practice. It in no way replaces the professional judgment of a pharmacist.
**CHOOSE MANUFACTURER-PREPARED SOLUTIONS AND PREMIX**

- **Multivitamins, Amino Acids and Lipids.** In the same way nutrients are an essential part of a patient’s TPN therapy, a pharmacy’s parenteral nutrition portfolio isn’t complete without a variety of nutrients for both adult and pediatric needs. Additionally, having a full selection supports your pharmacy’s efficiency and safety goals.

  **Multivitamins for Infusion**
  Multiple Vitamins for Infusion in both adult and pediatric presentations or formulations, containing low aluminum and zero preservatives. Comes in single-dose and pharmacy bulk packages.

  **Amino Acid Injections**
  Broad range of sulfite-free Amino Acid Injections from 6% to 10% Pediatric and 10%, 15% and 20% Adult Solution concentrations in flexible containers. The only 20% concentration option available.

  **IV Fat Emulsion**
  IV Fat Emulsion available in a variety of concentrations and volumes.
CLINIMIX and CLINIMIX E Injections. The leading manufacturer-prepared PN solution available with and without electrolytes in a lipid-compatible container.

Indications

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections and CLINIMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections are indicated as a caloric component in a parenteral nutrition regimen and as the protein (nitrogen) source for offsetting nitrogen loss or for the treatment of negative nitrogen balance in patients where

1. the alimentary tract cannot or should not be used,
2. gastrointestinal absorption of protein is impaired, or
3. metabolic requirements for protein are substantially increased, as with extensive burns.

Important Risk Information

- It is essential that a carefully prepared protocol based on current medical practices be followed, preferably by an experienced team. Frequent clinical evaluation and laboratory determinations are necessary for proper monitoring during administration. CLINIMIX and CLINIMIX E Injections are contraindicated in patients having intracranial or intraspinal hemorrhage, in patients who are severely dehydrated, in patients hypersensitive to one or more amino acids and in patients with severe liver disease or hepatic coma. Solutions containing corn-derived dextrose may be contraindicated in patients with known allergy to corn or corn products.

- Because of the potential for life-threatening events, caution should be taken to ensure that precipitates have not formed in any parenteral nutrient admixture.

- Use with caution when administering to patients with anuria or renal insufficiency, pulmonary insufficiency, or heart disease. The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. Metabolic complications have been reported, such as acid-base, electrolyte, and blood glucose imbalances, elevated liver enzymes, and osmotic diuresis and dehydration.

- Other adverse reactions that may occur include febrile response, infection at the site of injection, extravasation, and hypervolemia. The infusion of hypertonic nutrient injections into a peripheral vein may result in vein irritation, vein damage, and thrombosis.

- This product contains aluminum that may be toxic with prolonged parenteral administration if kidney function is impaired.

- CLINIMIX and CLINIMIX E Injections must be admixed prior to infusion.

Please see accompanying full Prescribing Information.

A Premix Option for Flexible PN Therapy. Data shows that 78 percent of adult PN orders could be filled with CLINIMIX Injections formulas based on daily needs of protein, calories, and volume.

- Up to 100 g of protein in a 2 L bag
- 1 and 2 L volumes
- Multi-chamber bag allows for two-in-one or three-in-one admixtures
- Appropriate for adult and pediatric patients
- An essential component of your dual PN system
- Available for immediate needs
  - First dose or starter bags
  - Backup system
  - After hours / weekends
- Manufactured following Current Good Manufacturing Practices (cGMP)
CHOOSE THE LEADING COMPOUNDING SYSTEM

Designed to help expedite production with ease and accuracy. The EXACTAMIX Compounder is an automated pumping system that compounds multiple sterile ingredients into a finished solution in a single patient bag.

- Helps reduce the need for manual additions by pumping volumes as low as 0.2 mL
- Produces a 3-liter bag in approximately 4.5 minutes
- Designed for cosigner validation of right drug / right port, the once daily setup includes a Prime and Verify process
- Facilitates compliance with detailed reporting on calibration activities, pumping accuracy and individual patient formulas
- Compounds TPN, CRRT, cardioplegia, base solutions, epidurals
EXACTAMIX Valve Sets, EVA Bags and Inlets are Rx Only. The compounder software is not intended to replace the professional judgment or knowledge of a pharmacist or pharmacy technician.
DoseEdge Pharmacy Workflow Manager

- Alerts technicians to help identify compounding errors before they happen
- Enables remote pharmacist verification from web-enabled devices on the hospital’s network
- Documents and stores key preparation details, including dose calculations, lot numbers and expiration dates
- Provides continuous visibility to the status and location of doses

For safe and proper use of the DoseEdge System, please refer to the appropriate manual.

The DoseEdge System is not intended to replace knowledge, judgment or expertise of pharmacists and pharmacy technicians in the preparation of IV admixtures or oral liquid doses.
CHOOSE THE RIGHT RESOURCES

Baxter’s Nutrition Specialists are available to help you customize a parenteral nutrition portfolio that best meets your needs.

Our Clinical Support team can analyze your current practice and recommend process improvements as well.

Inservice training and support helps to ease the transition process.

24/7 Technical Support for EXACTAMIX and ABACUS: 800-678-2292; or email: COTechsupport@baxter.com

➢ To learn more and create your custom portfolio of PN products, contact your Baxter representative or call 1-888-229-0001.
For all drugs mentioned herein please refer to the manufacturer’s package insert for full Prescribing Information.
Pediatric Use: Use of CLINIMIX E sulfite-free (Amino Acids with Electrolytes in Dextrose with Calcium) Injections is intended for intravenous use. See Table 1 for composition, pH, osmolarity, ionic concentrations and caloric supply.

Central Vein Administration: Hypersensitivity reactions of amino acids/electrolytes/dextrose with calcium injections may be administered safely, but continuous infusion through a central vein catheter with the lid for the product is recommended. In addition to measuring electrolytes, the catheter is intended for aseptic administration. Central venous access should be recommended to the patient for tolerance to dosages, as indicated by frequent determinations of urine and blood levels. Daily intake of amino acids and electrolytes/dextrose with calcium solutions should be increased gradually to the maximum required dose.

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Pediatric Use:

Nursing Mothers:

Electrolytes in Dextrose with Calcium) Injections should be given to a pregnant woman on fertility.

Pregnancy:

Metabolic:

The following metabolic complications have been reported:

Safety and effectiveness of CLIMMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections in pediatric patients has not been established by adequate and well-controlled studies. However, the use of amino acid injections in pediatric patients as an adjunct in the prevention of ketoacidosis in the treatment of equine ketoacidosis is referenced in the literature. See Dosage and Administration.

Geriatric Use: Clinical trials of CLIMMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, geriatric patients may be more susceptible to drug-related events, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease and drug therapy.

Adverse Reactions

See Warnings and Precautions.

Hypervitaminosis, electrolyte imbalances, and hyperammonemia. Frequent clinical renal function abnormalities may be recognized, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease and drug therapy.

Adverse Reactions

See Warnings and Precautions.

Renal:

Fluid and Electrolyte Imbalances

The composition of CLIMMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections is designed to meet specific fluid and electrolyte requirements in adult patients. if an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

If a patient is to be fed and maintained for a prolonged period of time, institution of parenteral nutrition should be considered.

Total daily dose of CLIMMIX E sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections depends on the patient's metabolic requirement and clinical response. The determination of chloride balance and accurate daily body weights, corrected for fluid balance, are probably the best means of determining individual therapeutic requirements.

Recommended Dietary Allowances*of proteins range from approximately 0.75 g/kg body weight for adults to 1.2 g/kg body weight for infants in the neonatal period. It may be necessary to add quantities of this electrolyte to these admixed injections, extending from the site of injection, extravasation, and hypervolemia. Policies and procedures should be established for the recognition and management of such reactions.

Total daily fluid requirements can be met beyond the volume of amino acids solution by supplementing with nasoenteral/biliary or enteral tube feedings.

In many patients, provision of adequate calories in the form of hypertonic dextrose may be required. Intravenous fat emulsions provide approximately 1 kcal per mL (10%), 2 kcal per mL (20%), or 3 kcal per mL (30%) and may be admixed along with amino acid with electrolytes/calcium injections in the CLIMMIX E/CLIMMIX C/CLIMMIX V/Caplet Container to supplement caloric intake.

Fat emulsion administration should be considered when prolonged (more than 5 days), persistent diarrhea or nausea occurs or when parenteral nutrition and electrolyte deficiency (PNE) occurs. Serum lipids should be monitored for evidence of ETD if patients maintained on fat emulsions for >2 weeks.

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Fat and Nutrition Board National Academy of Sciences - National Research Council (Revised 1989).

Table 1

<table>
<thead>
<tr>
<th>Contents of Admixed Product</th>
<th>Water</th>
<th>Fat</th>
<th>Amino Acids</th>
<th>Electrolytes</th>
<th>Total Caloric Content (kcal/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fat</strong></td>
<td>HEP</td>
<td>20%</td>
<td>4%</td>
<td>5%</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Amino Acids</strong></td>
<td></td>
<td></td>
<td>10%</td>
<td>15%</td>
<td>30%</td>
</tr>
<tr>
<td><strong>Electrolytes</strong></td>
<td></td>
<td></td>
<td>5%</td>
<td>7%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Total Caloric Content</strong></td>
<td></td>
<td></td>
<td>10%</td>
<td>15%</td>
<td>30%</td>
</tr>
</tbody>
</table>
**Figure 2**

Upon mixing of bag contents, CLINIMIX Injection solutions remain stable when stored under refrigeration for up to 9 days. If removed from the overwrap and the contents are not mixed, CLINIMIX Injection solutions must be stored at room temperature (25°C/77°F): brief exposure up to 40°C/104°F does not exceed twice normal serum osmolarity (718 mOsmol/L).

SEAL BETWEEN CHAMBERS. After opening the seal between the chambers and mixing thoroughly, the admixed product is intended for intravenous use. See Table 1 for composition, pH, osmolality, and concentration of the final admixture. Solution administrations by peripheral vein should not exceed twice normal serum osmolarity (718 mOsmol/L).

**Warnings**

Do not use if overwrap has been previously opened or damaged.

**Storage**

Store at 2°C to 8°C (36°F to 46°F). Do not freeze. Solutions in the admixture must be stored under refrigeration and limited to a brief exposure up to 40°C/104°F does not exceed twice normal serum osmolarity (718 mOsmol/L). Hypertonic mixtures of amino acid/dextrose injections should only be administered through an indwelling intravenous catheter with the tip located in a large central vein, such as the superior vena cava. If hyperosmolar blood is inadvertently drawn into the patient's circulation, hyperglycemia may result.

These CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections, admixed prior to administration, present special issues associated with retention of electrolytes. Chloride concentrations should be increased if required to meet normal serum chloride concentrations.

**Additive Considerations**

Additives should be used with caution. The use of fluids other than sterile water for injection is not recommended because of the risk of bacterial contamination. Additives can be introduced to the container. Mixing of admixtures is recommended. Do not mix with live vaccines.

**Clinical Pharmacology**

The CLARITY Dual Chamber Container is a lipid-compatible plastic container (Fig. 2). The amount of water that can permeate from inside the container into the environment is insufficient to affect the solution significantly. Solute content in contact with the plastic container may reach or exceed certain threshold components from the plastic in very small amount. However, testing does not support the safety of the plastic container material.

**Indications and Usage**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are indicated as a component in parenteral nutrition regimens and as the protein (amino acid) source for children requiring long-term parenteral nutrition. They should be used in patients who are unable to meet the increased amino acid requirements associated with catabolic states, such as with extensive burns.

**Warnings**

Additives may be incompatible. Supplemental rehydration should be added with a 10 to 18 gauge needle through the admixture port.

1. Suspend container from eyelet support.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port.
3. Attach transfer set to fat emulsion bottle, using aseptic technique.
4. Check for leaks.
5. Attach the transfer set to the exposed additive port. Check for leaks.
6. Open clamp on transfer set.
7. After completing transfer, use appropriate plastic clamp or needle to seal off transfer set.
8. Remove transfer set.

Solutions containing corn-derived dextrose may be contaminated in patients with known reactions to corn or corn products.

**Precautions**

Use with caution when administering to patients with acute or renal failure. Do not use if overwrap has been opened or damaged.

**Indications and Usage**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections, admixed prior to administration, present special issues associated with retention of electrolytes. Administration of amino acid solutions in the presence of impaired renal function presents special issues associated with retention of electrolytes. Hypertonic solutions should only be administered through an indwelling intravenous catheter with the tip located in a large central vein, such as the superior vena cava. If hyperosmolar blood is inadvertently drawn into the patient's circulation, hyperglycemia may result.

**Preparations for Administration**

Never use hypodermic needle equipment such as needles, syringes, and scalpels to puncture the overwrap for admixture preparation. Proper administration of these admixed amino acid/dextrose injections requires a knowledge of fluid and electrolyte balance and nutrition as well as clinical expertise in recognition and management of the complications which may occur.

**Indications and Usage**

CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are intended for a component in a parenteral nutrition regimen and as the protein (amino acid) source for children requiring long-term parenteral nutrition. They should be used in patients who are unable to meet the increased amino acid requirements associated with catabolic states, such as with extensive burns.
Metabolism: The following metabolic complications have been reported: metabolic acidosis, hypoglycemia, anaphylaxis, hyperglycemia and glucosuria, osmotic diuresis and dehydration, related hypoglycemia, unusual liver enzymes, and subclinical diabetes mellitus.

Frequent clinical evaluation and laboratory determinations are necessary, especially during the first few days of therapy to prevent or minimize these complications. Caution must be exercised in the administration of these amino acid and dextrose injections to patients receiving corticosteroids or corticotropin.

These admixed solutions should be used with caution in patients with overt or latent subclinical diabetes mellitus.

Drug product contains no more than 25 mcg/mL of aluminum.

Carcinoembryonic, Mutagenesis, Impairment of Fertility: Studies with CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C: Animal reproduction studies have not been conducted with CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections. It is not known whether these amino acid injections in the CLARITY Container to supplement caloric intake. Depending upon the clinical condition of the patient, approximately 3 liters of solution may be administered per 24 hour period. When used postoperatively, the therapy should begin with 1000 mL on the first postoperative day. Thereafter, the dose may be increased to 2000 mL, per day.

Do not administer amino acids unavailable between chambers is opened, other seals are intact, and solution is clear and thoroughly mixed.

Preparation: Drug product should be used immediately after dilution.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. In the informed judgment of the physician, it is deemed advisable to introduce new or different additives, new saline techniques. If thoroughly studied additives have been introduced. Do not store solutions containing additives. These amino acid solutions with electrolytes/ non-electrolytes/ vitamins/ minerals/ enzymes/ antibiotics added with additives should be under refrigeration and limited to a brief period of time, less than 24 hours.

Table 1

<table>
<thead>
<tr>
<th>Content of Administered Product</th>
<th>Calories (kcal/L)</th>
<th>Nonessential Amino Acids (mg/L)</th>
<th>Essential Amino Acids (mg/L)</th>
<th>Osmolarity (cal)</th>
<th>pH</th>
<th>Chloride (mEq/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>From Amino Acids</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Aspartic acid</td>
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<td>170</td>
<td>28</td>
<td>680</td>
<td>7.0</td>
<td>850</td>
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<tr>
<td>Glutamic acid</td>
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<td>170</td>
<td>28</td>
<td>680</td>
<td>7.0</td>
<td>850</td>
</tr>
<tr>
<td>Alanine</td>
<td>42</td>
<td>170</td>
<td>28</td>
<td>680</td>
<td>7.0</td>
<td>850</td>
</tr>
<tr>
<td>Valine</td>
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<td>170</td>
<td>28</td>
<td>680</td>
<td>7.0</td>
<td>850</td>
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<tr>
<td>Methionine</td>
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<td>6</td>
<td>880</td>
<td>7.0</td>
<td>1250</td>
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<tr>
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<td>170</td>
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<tr>
<td>Leucine</td>
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<td>170</td>
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<td>Phenylalanine</td>
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<td>Histidine</td>
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<td>Lysine</td>
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<td>0</td>
<td>0</td>
<td>7.0</td>
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</tr>
</tbody>
</table>

Dosage and Administration

The daily dose of CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections depends on the patient's metabolic requirement and clinical response. The determination of nitrogen balance and adequately body weight, corrected for fluid balance, are probably the best means of assessing individual nitrogen requirements.

Recommended Dietary Allowances of protein range from approximately 0.75 g/kg of body weight for adults to 1.0 g/kg for infants up to three months of age. It should be recognized, that protein as well as caloric requirements in traumatized or malnourished patients may be increased substantially. Daily amino acid doses of approximately 1.0 to 2.5 g/kg of body weight for adults with adequate caloric intake are generally sufficient to satisfy protein needs and promote positive nitrogen balance. For the initial treatment of trauma or protein calorie malnutrition, higher doses of protein with corresponding quantities of carbohydrate will be necessary to promote adequate nitrogen and energy balance. The need for additional fluid and electrolyte consideration is determining proper dose level. Such higher doses, especially in infants, must be accompanied by more frequent laboratory evaluation.

Care should be exercised to insure the maintenance of proper levels of serum potassium. Quantities of 80 to 100 mEq of potassium per day have been used with adequate clinical effect. If it is not necessary to add quantities of this electrolyte to these admixed solutions, depending primarily on the amount of electrolytes administered and excreted by the patient.

Patients receiving CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections without electrolytes should be monitored frequently and their electrolyte requirements individualized.

Total daily fluid requirements may be met beyond the volume of amino acid solution by supplementing with noncarbohydrate or carbohydrate-containing electrolyte solutions. Maintenance intravenous, additional electrolytes, and trace elements should be administered as required.