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Amino Acid Injections

PREMASOL 10%
CALCIUM PHOSPHATE SOLUBILITY

Calcium and phosphate solubility data for PN solutions containing PREMASOL 10% sulfite-free (amino acid) injection.

STUDY THE RESULTS

The data reflects the ranges of calcium phosphate concentrations that are less likely to precipitate.

Test samples were analyzed and compared to current USP <788> Instrumental Particulate Matter in Injections limits.

PREMASOL 10% sulfite-free (amino acid) injection is indicated for the nutrition support of infants (including those of very low birth weight) and young children requiring TPN via central or peripheral infusion routes. Parenteral nutrition with PREMASOL injection is indicated to prevent nitrogen and weight loss or treat negative nitrogen balance in infants and young children where: (1) the alimentary tract, by the oral, gastrostomy, or jejunostomy route, cannot or should not be used or adequate protein intake is not feasible by these routes, (2) gastrointestinal absorption of protein is impaired, or (3) protein requirements are substantially increased, as with extensive burns. Dosage, route of administration, and concomitant infusion of non-protein calories are dependent on various factors, such as nutritional and metabolic status of the patient, anticipated duration of parenteral nutrition support, and vein tolerance.

Please click here for Important Risk Information.

Click here for Full Prescribing Information for PREMASOL 10%.

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Study the Results

Table 1: Calcium Phosphate Solubility Curve boundary points for solutions made with PREMASOL (no added Cysteine)

1% PREMASOL 10% Dextrose Final concentration		**2% PREMASOL** 20% Dextrose Final concentration		**3% PREMASOL** 20% Dextrose Final concentration	
Calcium [mEq/L]	**Phosphate** [mMol/L]	**Calcium** [mEq/L]	**Phosphate** [mMol/L]	**Calcium** [mEq/L]	**Phosphate** [mMol/L]
37	9	30	19	50	14
35	11	25	21	40	17
17	17	22	22	17	25
5	35	18	25	15	40
3	45	10	35	9	50

Table 2: Calcium Phosphate Solubility Curve boundary points for solutions made with PREMASOL (with Cysteine)

1% PREMASOL Cysteine 40 mg/g amino acid 10% Dextrose Final concentration		**2% PREMASOL** Cysteine 40 mg/g amino acid 20% Dextrose Final concentration		**3% PREMASOL** Cysteine 40 mg/g amino acid 20% Dextrose Final concentration	
Calcium [mEq/L]	**Phosphate** [mMol/L]	**Calcium** [mEq/L]	**Phosphate** [mMol/L]	**Calcium** [mEq/L]	**Phosphate** [mMol/L]
45	18	35	30	60	30
25	23	31	31	45	32
21	26	18	41	36	36
8	35	12	50	15	50
6	45				

Figure 1: Calcium Phosphate Solubility Curves for PREMASOL NO added Cysteine

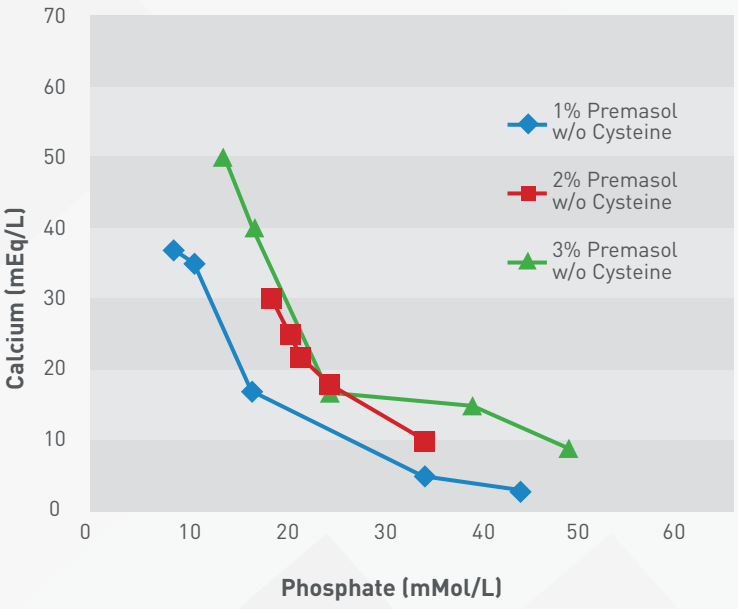
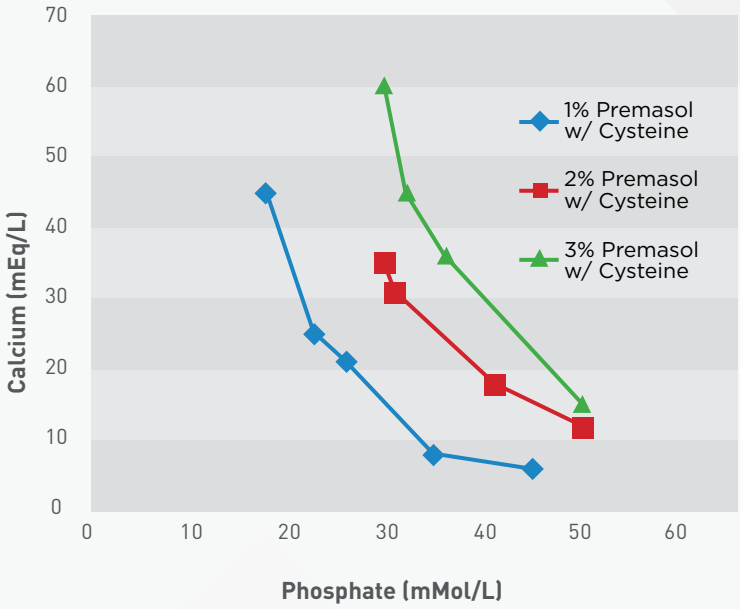


Figure 2: Calcium Phosphate Solubility Curves for PREMASOL with 40 mg of Cysteine per gram of amino acid



The area to the left and/or below each curve represents concentrations of calcium and phosphate that are more likely soluble, and data points to the right and/or above each curve represent concentrations of calcium and phosphate that are more likely to precipitate (Incompatibility Zone). These solubility curves are meant to serve as only a guide and are not intended to replace good clinical judgment.

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PREMASOL 10% sulfite-free (amino acid) injection Benefits:

- Indicated for the nutritional support of infants
- Plastic packaging helps to minimize breakage
- Sulfite-free formula reduces risk of sulfur allergies
- Multiple volume options

Stay Up to Date

- ✓ Evaluate PREMASOL injection for your patient needs
- ✓ Add PREMASOL injection calcium phosphate data to your electronic systems

For assistance in ABACUS Software, please contact Technical Support at 1-800-678-2292.

Ordering information

Product Code	Description	Container Volume	Units Per Case	National Drug Code	ABC	Cardinal	McKesson Drug	Morris Dickson	HD Smith	Owens & Minor
2B0012	PREMASOL 10% sulfite-free (amino acid) injection	500 mL	24	0338-1130-03	10060842	3695293	1345172	638783	1902816	07062B0012
2B0009	PREMASOL 10% sulfite-free (amino acid) injection	1000 mL	12	0338-1130-04	10053877	3501566	1994177	499285	1456003	07062B0009
2B0010	PREMASOL 10% sulfite-free (amino acid) injection	2000 mL	6	0338-1131-06	N/A	3501574	1994193	499293	1456011	07062B0010

Call your Baxter sales representative for more product information.

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Click here for Full Prescribing Information for PREMASOL 10%.

Indications and Important Risk Information PREMASOL 10%

Indications

PREMASOL 10% sulfite-free (amino acid) injection is indicated for the nutrition support of Infants (including those of very low birth weight) and young children requiring TPN via central or peripheral infusion routes. Parenteral nutrition with PREMASOL injection is indicated to prevent nitrogen and weight loss or treat negative nitrogen balance in infants and young children where: (1) the alimentary tract, by the oral, gastrostomy, or jejunostomy route, cannot or should not be used or adequate protein intake is not feasible by these routes, (2) gastrointestinal absorption of protein is impaired, or (3) protein requirements are substantially increased, as with extensive burns. Dosage, route of administration, and concomitant infusion of non-protein calories are dependent on various factors, such as nutritional and metabolic status of the patient, anticipated duration of parenteral nutrition support, and vein tolerance.

Important Risk Information

- PREMASOL 10% injection is contraindicated in patients with untreated anuria, hepatic coma, inborn errors of amino acid metabolism, including those involving branched chain amino acid metabolism such as maple syrup urine disease and isovaleric acidemia, or hypersensitivity to one or more amino acids in the solution.
- **This injection is for compounding only, not for direct infusion**
- Safe, effective use of parenteral nutrition requires knowledge of nutrition as well as clinical expertise in recognition and treatment of the complications which can occur.
- **Frequent evaluation and laboratory determinations are necessary for proper monitoring of parenteral nutrition.** Depending on the patient's conditions or disease state, additional electrolyte supplementation may be required.
- Fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema can occur with IV administration.
- Administration of amino acids in patients with impaired renal function or gastrointestinal bleeding may augment an already elevated blood urea nitrogen. Do not infuse amino acids in patients with azotemia.
- Administration of amino acid solutions to a patient with hepatic insufficiency may result in plasma amino acid imbalances, hyperammonemia, prerenal azotemia, stupor and coma.
- It is essential that blood ammonia be measured frequently in infants. Hyperammonemia in the syndrome is caused by genetic metabolic defects and is sometimes associated, although not necessarily in a causal relationship, with mental retardation. This reaction appears to be dose related and is more likely to develop during prolonged therapy. Should symptoms of hyperammonemia develop, amino acid administration should be discontinued and patient's clinical status reevaluated.
- This product contains aluminum that may be toxic with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.
- Strongly hypertonic nutrient solutions should be administered via an intravenous catheter placed in a central vein, preferably the superior vena cava.
- Special care must be taken when giving hypertonic dextrose to patients with diabetes or impaired glucose tolerance. To prevent hyperglycemia in such patients, insulin may be required.
- The final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.
- Adverse reactions reported in clinical studies were: water weight gain, edema, increase in BUN, and mild acidosis. Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypovolemia. Phosphorus deficiency may lead to impaired tissue oxygenation and acute hemolytic anemia. Relative to calcium, excessive phosphorous intake can precipitate hypocalcemia with cramps, tetany, and muscular hyperexcitability. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic counter measures and save the remainder of the fluid for examination, if deemed necessary.
- Protect from light until immediately prior to use.

Click here for Full Prescribing Information for PREMASOL 10%

Full Prescribing Information is also available at www.baxterpi.com

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