Baxter

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

Introducing new additions to our **Clinimix** family

CLINIMIX (amino acids in dextrose) Injections and **CLINIMIX E** (amino acids with electrolytes in dextrose with calcium)

AVAILABLE IN CLARITY DUAL CHAMBER CONTAINER

All **CLINIMIX** and **CLINIMIX E** formulations contain no more than 25 mcg/L Aluminum

PRODUCT	1 L CODE	1 L NDC	2 L CODE	2 L NDC	Amino Acid Concentration after mixing	Dextrose Concentration after mixing	Kcal / Liter: From Dextrose	Kcal / Liter: From Amino Acids	Kcal / Liter: TOTAL (Dextrose & Amino Acids)	g Amino Acid/Liter	Dextrose g/L	g Nitrogen/Liter	Electrolyte Profile[1]: Sodium (mEq/L)	Potassium (mEq/L)	Magnesium (mEq/L)	Calcium (mEq/L)	Acetate[2,3] (mEq/L)	Chloride[4,5] (mEq/L)	Phosphate (mMol/L)	Osmolarity (mOsmol/L) calc.	pH[6] (range 4.5 to 7.0)
CLINIMIX sulfite-free (amino acids in dextrose) Injections																					
CLINIMIX 4.25/5	2B7726	0338-1133-03	2B7704	0338-1089-04	4.25%	5%	170	170	340	42.5	50	7.02					37	17		675	6
CLINIMIX 4.25/10	2B7727	0338-1134-03	2B7705	0338-1091-04	4.25%	10%	340	170	510	42.5	100	7.02					37	17		930	6
CLINIMIX 5/15	2B7730	0338-1137-03	2B7709	0338-1099-04	5%	15%	510	200	710	50	150	8.26					42	20		1255	6
CLINIMIX 5/20	2B7731	0338-1138-03	2B7710	0338-1101-04	5%	20%	680	200	880	50	200	8.26					42	20		1505	6
CLINIMIX 6/5	EADB9913	0338-0198-06	N/A	N/A	6%	5%	170	240	410	60	50	9.9					53	24		850	6
CLINIMIX 8/10	EADB9933	0338-0188-06	EADB9935	0338-0194-04	8%	10%	343	320	663	80	100	13.2					71	32		1308	6
CLINIMIX 8/14	EADB9953	0338-0180-06	EADB9955	0338-0184-04	8%	14%	477	320	797	80	140	13.2					71	32		1520	6
CLINIMIX E sulfite-free (amino acids with electrolytes in dextrose with calcium) Injections																					
CLINIMIX E 2.75/5	2B7735	0338-1142-03	N/A	N/A	2.75%	5%	170	110	280	27.5	50	4.54	35	30	5	4.5	51	39	15	665	6
CLINIMIX E 4.25/5	2B7737	0338-1144-03	2B7716	0338-1113-04	4.25%	5%	170	170	340	42.5	50	7.02	35	30	5	4.5	70	39	15	815	6
CLINIMIX E 4.25/10	2B7738	0338-1145-03	2B7717	0338-1115-04	4.25%	10%	340	170	510	42.5	100	7.02	35	30	5	4.5	70	39	15	1070	6
CLINIMIX E 5/15	2B7740	0338-1147-03	2B7721	0338-1123-04	5%	15%	510	200	710	50	150	8.26	35	30	5	4.5	80	39	15	1395	6
CLINIMIX E 5/20	2B7741	0338-1148-03	2B7722	0338-1125-04	5%	20%	680	200	880	50	200	8.26	35	30	5	4.5	80	39	15	1650	6
CLINIMIX E 8/10	EADB9943	0338-0210-06	EADB9945	0338-0214-04	8%	10%	343	320	663	80	100	13.2	35	30	5	4.5	83	76	15	1450	6
CLINIMIX E 8/14	EADB9963	0338-0202-06	EADB9965	0338-0206-04	8%	14%	477	320	797	80	140	13.2	35	30	5	4.5	83	76	15	1650	6

1. Balanced by ions from amino acids.
2. Derived from glacial acetic acid (for pH adjustment) in CLINIMIX.
3. Derived from glacial acetic acid (for pH adjustment) and sodium acetate in CLINIMIX E.
4. Contributed by the lysine hydrochloride in CLINIMIX.
5. Contributed by calcium chloride, lysine hydrochloride, magnesium chloride, and sodium chloride in CLINIMIX E.
6. pH of sulfite-free Amino Acid Injection and sulfite-free Amino Acid Injection with Electrolytes in the outlet port chamber was adjusted with glacial acetic acid.

Please see reverse side for Indications, 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. Preter m 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.

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