

THE CLINIMIX PORTFOLIO HELPS YOU NOURISH MORE PATIENTS WITH MCB-PN

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

All **CLINIMIX** and

AVAILABLE IN CLARITY DUAL CHAMBER CONTAINER			CLINIMIX E formulations contain no more than 25 mcg/L Aluminum			Concentration ng	rose	o Acids	& Amino Acids]	Acid/Liter	g/L	/Liter	(mEq/L)	ı (mEq/L)	n (mEq/L)	[mEq/L]	[mEq/L]	[mEq/L]	e (mMol/L)	y L] calc.	je 4.5 to 7.0)
PRODUCT	1 L CODE	1 L NDC	2 L CODE	2 L NDC	Amino Acid C after mixing	Dextrose Cor after mixing	From Dextrose	From Amino	TOTAL (Dextrose	g Amino Ac	Dextrose ç	g Nitrogen/Liter	Sodium (n	Potassium	Magnesiur	Calcium (n	Acetate ^{2,3}	Chloride ^{4,5}	Phosphate	Osmolarity [mOsmol/L]	pH ^{6,7} (range
CLINIMIX (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 (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

15%

20%

10%

14%

5%

5%

CLINIMIX E 5/15

CLINIMIX E 5/20

CLINIMIX E 8/10

CLINIMIX E 8/14

2B7740

2B7741

EADB9943

EADB9963

0338-1147-03

0338-1148-03

0338-0210-06

0338-0202-06

2B7721

2B7722

EADB9945

EADB9965

200

200

710

880

510

680

Kcal / Liter

Electrolyte Profile1

1395

1650

15

15

39

50

50

150

200

8.26

8.26

35

35

30

4.5

See next page for Indications and Important Risk Information. Click here for accompanying full Prescribing Information for Clinimix and Clinimix E.

0338-1123-04

0338-1125-04

0338-0214-04

0338-0206-04

^{1.} Balanced by ions from amino acids.

Derived from glacial acetic acid (for pH adjustment) in CLINIMIX.

Derived from glacial acetic acid (for pH adjustment) and sodium acetate in CLINIMIX E.

^{4.} Contributed by the lysine hydrochloride and hydrochloric acid (for pH adjustment) in CLINIMIX.

^{5.} Contributed by calcium chloride, lysine hydrochloride, magnesium chloride, sodium chloride, and hydrochloric acid in CLINIMIX E.

^{6.} pH of sulfite-free amino acid injection in the outlet port chamber may be adjusted with qlacial acetic acid and pH of dextrose injection port chamber may be adjusted with hydrochloric acid.

pH of sulfite-free amino acid injection with electrolytes in the outlet port chamber was adjusted with glacial acetic acid and pH of dextrose injection port chamber was adjusted with hydrochloric acid.

Indications and Important Risk 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. Excess 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. Protect the activated parenteral nutrition solution from light. 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 impaired
 kidney function. 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 impaired kidney function, 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 kidney disease 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.

Please click here for accompanying full Prescribing Information for <u>Clinimix</u>.

Please click here for accompanying full Prescribing Information for <u>Clinimix E</u>.

