

IMPORTANT DRUG INFORMATION

Subject: Missing linear barcode on the primary bag labels of certain lots of **Clinimix** and **Clinimix E** injections

October 2, 2024

Dear Healthcare Provider:

To avoid potential shortages of **Clinimix** and **Clinimix E** injections in the United States, Baxter Healthcare Corporation is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily distribute lots of **Clinimix** and **Clinimix E**, manufactured between February 2024 and September 2024, that are missing the linear barcode on the primary bag label (see Figure 1 below). The NDC number is still printed on the primary bag label. The linear barcode is used to identify the drug's name, strength, and volume. A two-dimensional barcode (see Figure 2 below), including the NDC number, expiry date, and lot number is present on the bag as a replacement; however, it may not be compatible with the IT systems used in your facility. This issue only impacts the product codes and lot numbers listed in Attachment A.

Potential risks associated with the absence of a linear barcode include:

- The lack of a linear barcode on affected products may cause a delay in therapy due to inability to scan the linear barcode and may lead to the wrong formulation of the **Clinimix** or **Clinimix E** injection being administered to a patient.
- Parenteral Nutrition (PN) preparations are high-alert medications because significant patient harm may occur when PN therapy is used incorrectly. The clinical results may include fluid and electrolyte disturbances as well as nutritional complications.
- The administration of the **Clinimix** and **Clinimix E** injection formulations through the wrong route could lead to venous complications such as thrombophlebitis.

To date, there have been no adverse events related to this issue, reported to Baxter.



Figure 1: Example of linear barcode which is missing from **Clinimix** and **Clinimix E**



Figure 2: Example of two-dimensional barcode

Affected Products

Product Code	Product Description	Lot Number	NDC Number
Refer to attachment A	Clinimix sulfite-free (Amino Acids in Dextrose) Injection	All lots with expiration dates through August 2026	Refer to attachment A
Refer to attachment A	Clinimix E sulfite-free (Amino Acids with Electrolytes in Dextrose with Calcium) Injection	All lots with expiration dates through August 2026	Refer to attachment A

Please follow the recommendations under “Actions to be Taken by Healthcare Providers” below to minimize the risk of confusion and medication errors, and to ensure the safe use of all affected lots of **Clinimix** and **Clinimix E** injection that do not contain a linear barcode.

Actions to be Taken by Healthcare Providers

1. Healthcare Providers may continue to safely use the impacted products.
2. To ensure proper and safe usage of the product:
 - If your facility has systems with the ability to read two-dimensional barcodes, please use the barcode on the primary bag label.
 - If your facility **does not have** systems with the ability to read two-dimensional barcode, please refer to the primary bag label containing the human-readable format of the NDC.
 - Confirm that the product information in your electronic medical records or hospital system matches the product that you have selected/received and follow your facility verification procedures.
3. **If you received this communication directly from Baxter, please acknowledge receipt of this notification by responding on our customer portal at <https://BaxterFieldActionCustomerPortal.onprocess.com> even if you do not have any remaining inventory.** Log in to the portal using the account number listed in the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.
4. If you purchased this product from a distributor or wholesaler, responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.
5. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to them and **check the associated box on the customer portal.**

Reporting Complaints and Adverse Events

Healthcare providers should report quality complaints or adverse events associated with the use of **Clinimix** and **Clinimix E** injections by:

- **Complaints:** Contacting Baxter Product Surveillance at the Baxter product feedback portal at <https://productfeedback.baxter.com>, or emailing Baxter at corporate_product_complaints_round_lake@baxter.com
- **Adverse Events:** Contacting Baxter Patient Safety by calling 866-888-2472 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday, or emailing USAT_Pharmacovigilance@Baxter.com

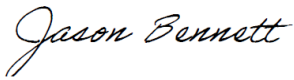
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail, or by fax:

- **Online:** Complete and submit the report online at: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.accessdata.fda.gov/scripts/medwatch/index.cfm or call 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 800-FDA-0178 (800-332-0178).

For clinical questions related to the safe and effective use of **Clinimix** and **Clinimix E** Injection, please contact Baxter Medical Information at Medinfo@baxter.com.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,



Jason Bennett
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Attachment A – Affected **Clinimix** and **Clinimix E** Lots
Baxter Customer Reply Form Instruction Sheet

Attachment A – Affected Clinimix and Clinimix E Lots

Product Code	Product Description	Lot Number	Expiration Date	NDC Number
2B7709L	Clinimix 5/15 sulfite-free (5% Amino Acids in 15% Dextrose) Injection, 2000 mL	24B13N50	31-Jan-26	0338-7011-01
2B7716L	Clinimix E 4.25/5 sulfite- free (4.25% Amino Acids with Electrolytes in 5% Dextrose with Calcium) Injection, 2000 mL	24E06N50	30-Apr-26	0338-7024-01
		24E06N50S1	30-Apr-26	
		24E06N50S2	30-Apr-26	
		24E08N51	30-Apr-26	
		24E08N51S1	30-Apr-26	
		24E21N50	30-Apr-26	
		24G03N50	30-Jun-26	
		24G03N51	30-Jun-26	
		24H23N50	31-Jul-26	
		24H27N50	31-Jul-26	
		24H27N51	31-Jul-26	
		24H28N50	31-Jul-26	
		24H28N51	31-Jul-26	
		24I06N51	31-Aug-26	
24I12N50	31-Aug-26			
2B7717L	Clinimix E 4.25/10 sulfite-free (4.25% Amino Acids with Electrolytes in 10% Dextrose with Calcium) Injection, 2000 mL	24F04N50	31-May-26	0338-7028-01
		24F04N51	31-May-26	
2B7721L	Clinimix E 5/15 sulfite- free (5% Amino Acids with Electrolytes in 15% Dextrose with Calcium) Injection, 2000 mL	24E07N50	30-Apr-26	0338-7032-01
		24E07N50S1	30-Apr-26	
		24E14N51	30-Apr-26	
		24E22N51	30-Apr-26	
		24E28N50	30-Apr-26	
		24E28N51	30-Apr-26	
		24H26N50	31-Jul-26	
		24H26N51	31-Jul-26	
		24I05N50	31-Aug-26	
		24I11N50	31-Aug-26	
		24I11N51	31-Aug-26	
24I19N50	31-Aug-26			
2B7722L	Clinimix E 5/20 sulfite-free (5% Amino Acids with Electrolytes in 20% Dextrose with Calcium) Injection, 2000 mL	24B06N50	31-Jan-26	0338-7036-01
		24B06N51	31-Jan-26	
		24B06N51S1	31-Jan-26	
		24B22N50	31-Jan-26	

Attachment A – Affected Clinimix and Clinimix E Lots

Product Code	Product Description	Lot Number	Expiration Date	NDC Number
2B7722L	Clinimix E 5/20 sulfite-free (5% Amino Acids with Electrolytes in 20% Dextrose with Calcium) Injection, 2000 mL	24E16N51	30-Apr-26	0338-7036-01
		24E22N50	30-Apr-26	
		24E23N50	30-Apr-26	
		24E30N51	30-Apr-26	
		24I19N51	31-Aug-26	
2B7735L	Clinimix E 2.75/5 sulfite-free (2.75% Amino Acids with Electrolytes in 5% Dextrose with Calcium) Injection, 1000 mL	24B15N50	31-Jan-26	0338-7020-01
		24B15N50S1	31-Jan-26	
		24B15N50S2	31-Jan-26	
2B7737L	Clinimix E 4.25/5 sulfite-free (4.25% Amino Acids with Electrolytes in 5% Dextrose with Calcium) Injection, 1000 mL	24E08N50	30-Apr-26	0338-7022-01
		24E15N50	30-Apr-26	
		24F27N50	31-May-26	
		24G02N50	30-Jun-26	
		24G09N50	30-Jun-26	
		24I06N50	31-Aug-26	
2B7740L	Clinimix E 5/15 sulfite-free (5% Amino Acids with Electrolytes in 15% Dextrose with Calcium) Injection, 1000 mL	24E29N50	30-Apr-26	0338-7030-01
2B7741L	Clinimix E 5/20 sulfite-free (5% Amino Acids with Electrolytes in 20% Dextrose with Calcium) Injection, 1000 mL	24B20N50	31-Jan-26	0338-7034-01