CEFOTAXIME- cefotaxime injection powder, for solution
SteriMax Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

IMPORTANT PRESCRIBING INFORMATION

December 11, 2024

Temporary Importation of Cefotaxime for Injection to Address Drug Shortage

Dear Healthcare Professional:

Due to the current critical shortage of Cefotaxime for Injection products in the United States (U.S.) market, SteriMax Inc. (SteriMax), in conjunction with Provepharm, Inc. (Provepharm) and Direct Success, Inc. (Direct Success) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of the drug. SteriMax has initiated temporary importation of non-FDA approved Cefotaxime for Injection (1 g/vial, and 2 g/vial) into the U.S. market. The Cefotaxime for Injection from SteriMax is marketed in Canada and is manufactured at an FDA-inspected facility that complies with current Good Manufacturing Practice requirements.

At this time, no other entity except Provepharm or its distributor Direct Success is authorized by the FDA to import or distribute SteriMax's Cefotaxime for Injection in the United States. FDA has not approved SteriMax's Cefotaxime for Injection in the United States.

Effective immediately, Provepharm will distribute the following presentations of SteriMax's Cefotaxime for Injection to address the critical shortage:

SteriMax Cefotaxime for Injection		
1 g/vial (as cefotaxime sodium)	DIN: 02434091 (Canada)	NDC 21586-011-2
2 g/vial (as cefotaxime sodium)	DIN: 02434105 (Canada)	NDC 21586-012-2

Note: DIN refers to Drug Identification Number for products approved by Health Canada

The barcode on the imported product label may not register accurately on the U.S. scanning systems. Institutions should manually input the imported product information into their systems and confirm that the barcode, if scanned, provides correct information. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

In addition, the packaging of the imported product does not include serialization information. SteriMax's Cefotaxime for Injection does not meet the Drug Supply Chain Security Act (DSCSA) requirements for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs.

The vial and carton labels will display the text used and approved for marketing the products in Canada with both English and French translations. It is important to note that there are differences in the format and content of the labeling between the US approved product and SteriMax's Cefotaxime for Injection. Please see the product comparison tables at the end of this letter.

Cefotaxime for Injection is available only by prescription in the U.S. Please refer to the package insert for the FDA-approved Cefotaxime for Injection drug product for full prescribing information.

Finally, please ensure that your staff and others in your institution who may be involved in the administration of Cefotaxime for Injection receive a copy of this letter and review the information.

If you have any questions about the information contained in this letter, any quality related problems, or questions on the use of SteriMax's Cefotaxime for Injection, please contact SteriMax Inc. Customer Service at 1-800-881-3550.

To place an order, please contact Direct Success at Distribution@DSuccess.com or 1-877-404-3338.

Healthcare providers should report adverse events associated with the use of SteriMax's Cefotaxime for Injection to Provepharm at 1-833-684-3234.

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

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

We remain at your disposal to answer any questions you may have about our product; and provide more information if needed.

Sincerely,

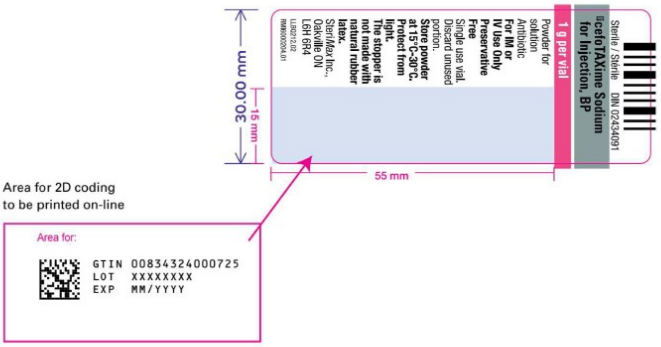
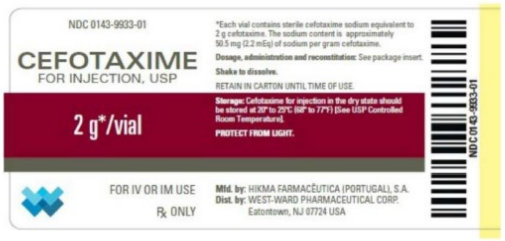
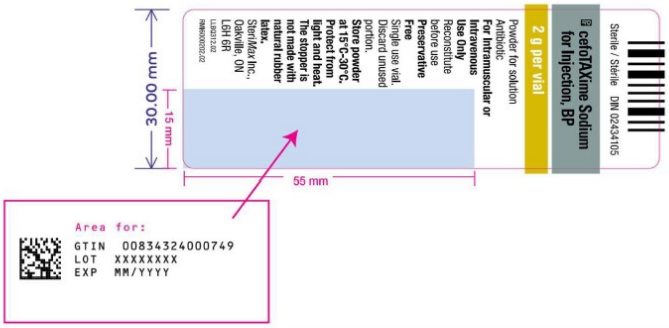
Signed by Ritesh Acharya
Ritesh Acharya | I approve this document
Dec 11, 2024 | 12:44:00 PM EST
Ritesh Acharya
F3EB2DA650A245FFB37A01A72CC340C7

Ritesh Acharya

Chief Scientific Officer

SteriMax Inc.

Product Comparison Table

	US FDA Approved Product	Import Product
Vial Container Label – 1 gram		
Vial Container Label – 2 gram		
Product Name	Cefotaxime for Injection, USP	PrcefoTAXime Sodium for Injection, BP
Route of Administration	For Intramuscular or Intravenous use	Intramuscular or Intravenous Use

	US FDA Approved Product	Import Product
Ingredients	**1 gram vial** Each vial contains sterile cefotaxime sodium equivalent to 1 g cefotaxime. The sodium content is approximately 50.5 mg (2.2 mEq) of sodium per gram cefotaxime. **2 gram vial** Each vial contains sterile cefotaxime sodium equivalent to 2 g cefotaxime. The sodium content is approximately 50.5 mg (2.2 mEq) of sodium per gram cefotaxime.	1 g per vial Cefotaxime sodium powder for solution 2 g per vial Cefotaxime sodium powder for solution
Compatibility and Storage	**Compatibility and Stability** Solutions of cefotaxime reconstituted as described above (**Preparation of cefotaxime for injection sterile**) remain chemically stable (potency remains above 90%) as follows when stored in original containers and disposable plastic syringes: Strength | Reconstituted Concentration mg/mL | Stability at or below 22°C | Stability under Refrigeration (at or below 5°C) Original Containers | Plastic Syringes 500 mg vial IM | 230 | 12 hours | 7 days | 5 days 1 g vial IM | 300 | 12 hours | 7 days | 5 days 2 g vial IM | 330 | 12 hours | 7 days | 5 days 500 mg vial IV | 50 | 24 hours | 7 days | 5 days 1 g vial IV | 95 | 24 hours | 7 days | 5 days 2 g vial IV | 180 | 12 hours | 7 days | 5 days Reconstituted solutions stored in original containers and plastic syringes remain stable for 13 weeks frozen. Reconstituted solutions may be further diluted up to 1000 mL with the following solutions and maintain satisfactory potency for 24 hours at or below 22°C, and at least 5 days under refrigeration (at or below 5°C): 0.9% Sodium Chloride Injection; 5 or 10% Dextrose Injection; 5% Dextrose and 0.9% Sodium Chloride Injection, 5% Dextrose and 0.45% Sodium Chloride Injection; 5% Dextrose and 0.2% Sodium Chloride Injection; Lactated Ringer's Solution; Sodium Lactate Injection (M/6); 10% Invert Sugar Injection, 8.5% TRAVASOL (Amino Acid) Injection without Electrolytes. Solutions of cefotaxime must not be admixed with aminoglycoside solutions. If cefotaxime and aminoglycosides are	**Solutions For i.v. Infusion:** Cefotaxime sodium for Injection, BP is compatible with the following infusion fluids: – 0.9% NaCl injection – 5% Dextrose injection – 0.9% NaCl and 5% Dextrose injection – 0.45% NaCl and 5% Dextrose injection – 0.2% NaCl and 5% Dextrose injection – Sodium Lactate injection – 5% Dextrose and 0.15% KCl injection – Plasma-Lyte 56 Electrolyte Solution in 5% Dextrose injection – Ringer's injection – Lactated Ringer's solution – Lactated Ringer's with 5% Dextrose injection **Incompatibilities:** Solutions of Cefotaxime sodium for Injection, BP must not be admixed aminoglycoside solutions. If Cefotaxime sodium for Injection, BP and aminoglycosides are to be administered to the same patient, they must be administered separately and not as a mixed injection. Solutions of Cefotaxime sodium for Injection, BP should not be prepared with diluents having a pH above 7.5 such as Sodium Bicarbonate Injection. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Solutions of Cefotaxime sodium for Injection, BP range from light yellow to amber, depending on concentration and diluent used. The dry powder as well as solutions tend to darken, depending on storage conditions. Cefotaxime sodium for Injection, BP reconstituted in the original vial as described under Reconstitution is chemically stable for 12 hours at room temperature (15-25°C) and for 24 hours under refrigeration (2-8°C). Only freshly prepared reconstituted solutions may be further diluted with 50 to 1000 mL of the recommended infusion fluids in

	US FDA Approved Product	Import Product
	to be administered to the same patient, they must be administered separately and not as mixed injection. **NOTE**: Cefotaxime solutions exhibit maximum stability in the pH 5-7 range. Solutions of cefotaxime should not be prepared with diluents having a pH above 7.5, such as Sodium Bicarbonate Injection. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.	VIAFLEX2 intravenous bags. Such solutions are chemically stable for 12 hours at room temperature (15-25°C) and for 24 hours under refrigeration (2-8°C). Any unused solutions should be discarded. From a microbiological point of view, this infusion preparation should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and cannot be longer than 24 hours at 2°C to 8°C or 12 hours at room temperature (15-25°C) when dilution has taken place in controlled and validated aseptic conditions. Solutions of Cefotaxime sodium for Injection, BP (cefotaxime sodium) range from light yellow to amber, depending on concentration and the diluent used. The solutions tend to darken depending on storage conditions and should be protected from elevated temperatures and excessive light. Cefotaxime sodium for Injection, BP solutions exhibit maximum stability in the pH 5-7 range.
Storage Conditions	Cefotaxime for Injection, USP in the dry state should be stored at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. The dry material as well as solutions tend to darken depending on storage conditions and should be protected from elevated temperatures and excessive light.	Cefotaxime sodium for Injection, BP in the dry state should be stored at room temperature (15-25°C), protected from light and heat. The dry powder as well as solutions tend to darken, depending on storage conditions.

Cefotaxime for Injection - 1 g per vial

Sterile/Stérile DIN 02434091

cefoTAXime Sodium for Injection, BP

1 g per vial

Powder for solution

Antibiotic

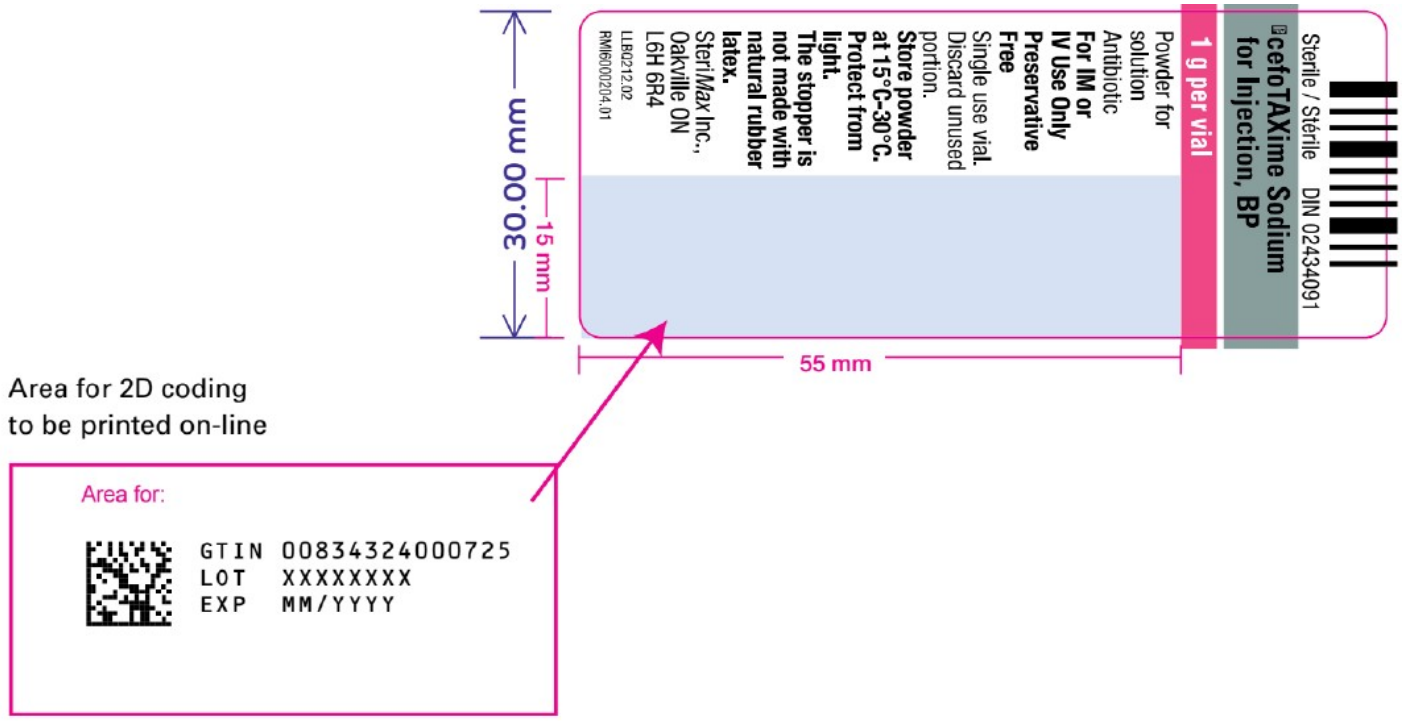
For IM or IV Use Only

Preservative Free

Single use vial. Discard unused portion.

The stopper is not made with natural rubber latex.

Steri*Max* Inc.



Cefotaxime for Injection - 2 g per vial

Sterile/Stérile DIN 02434105

cefoTAXime Sodium for Injection, BP

2 g per vial

Powder for solution

Antibiotic

For Intramuscular or Intravenous Use Only

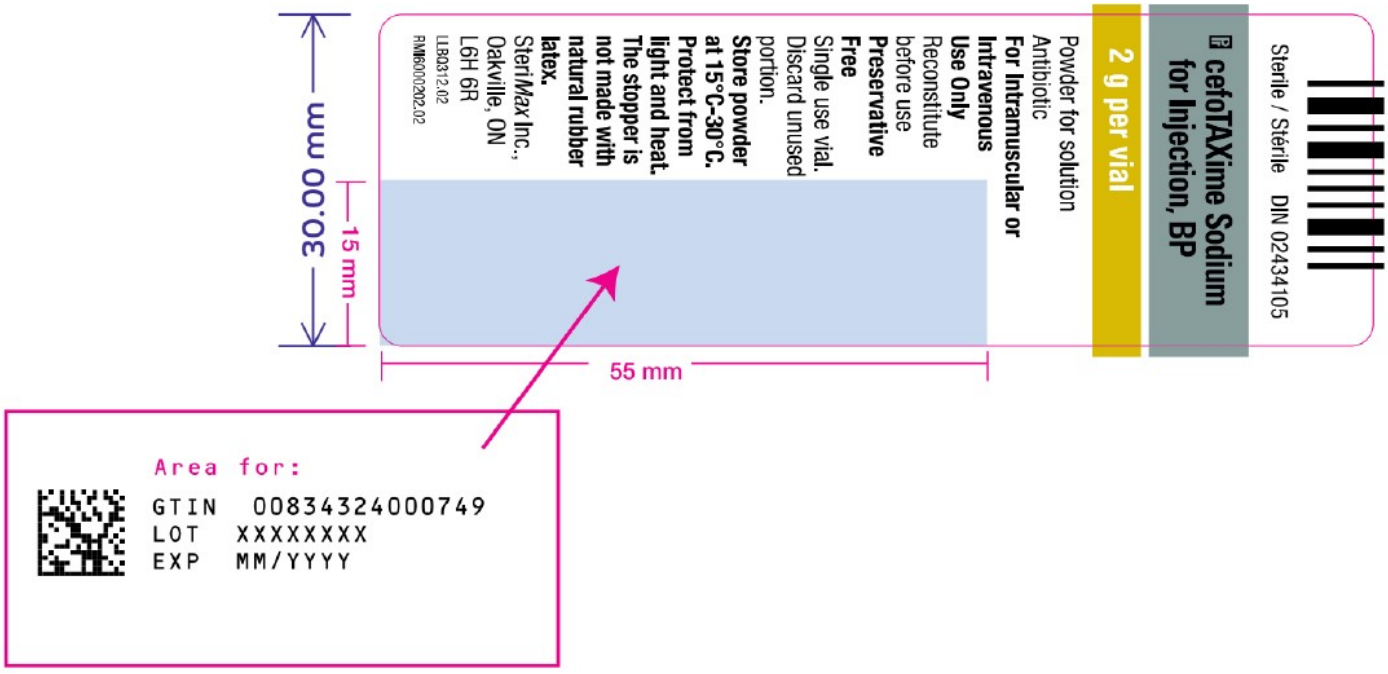
Reconstitute before use

Preservative Free

Single use vial. Discard unused portion.

The stopper is not made with natural rubber latex.

Steri*Max* Inc.



CEFOTAXIME

cefotaxime injection powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21586-011
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CEFOTAXIME SODIUM (UNII: 258J72S7TZ) (CEFOTAXIME - UNII:N2GI8B1GK7)	CEFOTAXIME	1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21586-011-02	10 in 1 PACKAGE	08/01/2019	
1	NDC:21586-011-01	1 in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		08/01/2019	

CEFOTAXIME

cefotaxime injection powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21586-012
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CEFOTAXIME SODIUM (UNII: 258J72S7TZ) (CEFOTAXIME - UNII:N2GI8B1GK7)	CEFOTAXIME	2 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21586-012-02	10 in 1 PACKAGE	08/01/2019	
1	NDC:21586-012-01	1 in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		08/01/2019	

Labeler - SteriMax Inc. (251574851)

Revised: 12/2024 SteriMax Inc.