

**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.

Temporary Imporation of Cefotaxime for Injection to Address Critical Drug Shortage

IMPORTANT PRESCRIBING INFORMATION

July 09, 2019

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 Apollo Pharmaceuticals USA Inc. (Apollo) and FFF Enterprises (FFF), 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 Apollo or its distributor FFF is authorized by the FDA to import or distribute SteriMaxs Cefotaxime for Injection in the United States. FDA has not approved SteriMaxs Cefotaxime for Injection in the United States.

Effective immediately, FFF will distribute the following presentations of SteriMaxs Cefotaxime for Injection to address the critical shortage:

SteriMax Cefotaxime for Injection	
1 g/vial (as cefotaxime sodium)	DIN: 02434091 (Canada)
2 g/vial (as cefotaxime sodium)	DIN: 02434105 (Canada)

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 FFF Enterprises at 1-800-843-7477.

Healthcare providers should report adverse events associated with the use of SteriMax's Cefotaxime for Injection to Apollo at 1-833-727-6556.

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,


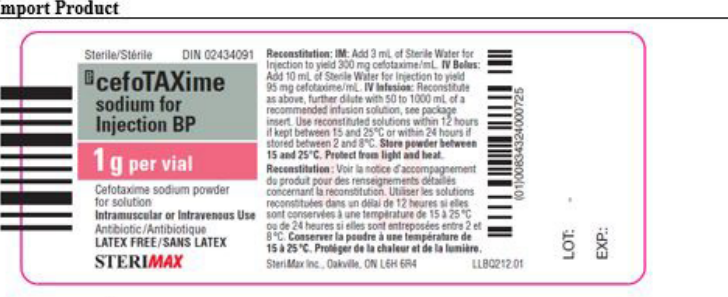




James Booker

Head of Quality

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	^P cefoTAXime sodium for Injection BP
Route of Administration	For IV or IM use	Intramuscular or Intravenous Use
Ingredients	<p>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.</p> <p>2 gram vial Each vial contains sterile cefotaxime sodium equivalent to 2 g cefotaxime. The sodium content is approximately 101 mg (4.4 mEq) of sodium per gram cefotaxime.</p>	<p>1 g per vial Cefotaxime sodium powder for solution</p> <p>2 g per vial Cefotaxime sodium powder for solution</p>

	US FDA Approved Product	Import Product																																															
Compatibility and Storage	<p>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:</p> <table border="1"> <thead> <tr> <th rowspan="2">Strength</th> <th rowspan="2">Reconstituted Concentration mg/ml</th> <th rowspan="2">Stability at or below 22°C</th> <th colspan="2">Stability under Refrigeration (at or below 5°C)</th> </tr> <tr> <th>Original Containers</th> <th>Plastic Syringes</th> </tr> </thead> <tbody> <tr> <td>500 mg vial IM</td> <td>230</td> <td>12 hours</td> <td>7 days</td> <td>5 days</td> </tr> <tr> <td>1 g vial IM</td> <td>300</td> <td>12 hours</td> <td>7 days</td> <td>5 days</td> </tr> <tr> <td>2 g vial IM</td> <td>330</td> <td>12 hours</td> <td>7 days</td> <td>5 days</td> </tr> <tr> <td>500 mg vial IV</td> <td>50</td> <td>24 hours</td> <td>7 days</td> <td>5 days</td> </tr> <tr> <td>1 g vial IV</td> <td>95</td> <td>24 hours</td> <td>7 days</td> <td>5 days</td> </tr> <tr> <td>2 g vial IV</td> <td>180</td> <td>12 hours</td> <td>7 days</td> <td>5 days</td> </tr> <tr> <td>1 g infusion bottle</td> <td>10-20</td> <td>24 hours</td> <td>10 days</td> <td>—</td> </tr> <tr> <td>2 g infusion bottle</td> <td>20-40</td> <td>24 hours</td> <td>10 days</td> <td>—</td> </tr> </tbody> </table> <p>Reconstituted solutions stored in original containers and plastic syringes remain stable for 13 weeks frozen.</p> <p>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.</p> <p>Solutions of cefotaxime must not be admixed with aminoglycoside solutions. If cefotaxime and aminoglycosides are to be administered to the same patient, they must be administered separately and not as mixed injection.</p> <p>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.</p>	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	1 g infusion bottle	10-20	24 hours	10 days	—	2 g infusion bottle	20-40	24 hours	10 days	—	<p>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</p> <p>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.</p> <p>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.</p> <p>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 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.</p>
	Strength				Reconstituted Concentration mg/ml	Stability at or below 22°C	Stability under Refrigeration (at or below 5°C)																																										
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	<p>US FDA Approved Product</p> <p>Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.</p> <p>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].</p> <p>The dry material as well as solutions tend to darken depending on storage conditions and should be protected from elevated temperatures and excessive light.</p>	<p>Import Product</p> <p>Cefotaxime sodium for Injection, BP solutions exhibit maximum stability in the pH 5-7 range</p> <p>Cefotaxime sodium for Injection, BP in the dry state should be stored at room temperature (15-25°C), protected from light and heat.</p> <p>The dry powder as well as solutions tend to darken, depending on storage conditions.</p>																																															

Cefotaxime for Injection - 1 g per vial

Sterile/Stérile DIN 02234091

cefoTAXime sodium for Injection BP

1 g per vial

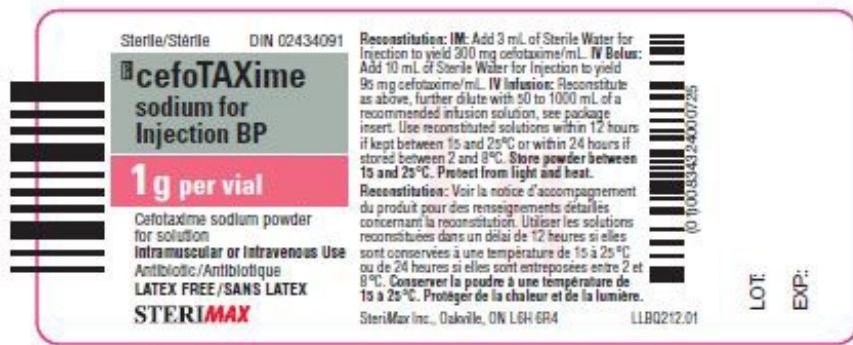
Cefotaxime sodium powder for solution

Intramuscular or Intravenous Use

Antibiotic/Antibiotique

LATEX FREE/SANS LATEX

STERIMAX



Cefotaxime for Injection - 2 g per vial

Sterile/Stérile DIN 02434105

cefoTAXime sodium for Injection BP

2 g per vial

Cefotaxime sodium powder for solution

Intramuscular or Intravenous Use

Antibiotic/Antibiotique

LATEX FREE/SANS LATEX

STERIMAX



CEFOTAXIME

cefotaxime injection powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:21586-0-11
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		

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Labeler - SteriMax Inc. (251574851)