Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Apotex Corp. Issues Voluntary Nationwide Recall of Piperacillin and Tazobactam For Injection, USP 3.375 Gram/Vial And 4.5 Gram/Vial Strengths Due to Elevated Levels of Impurities That May Result in Decreased Potency

For Immediate Release

May 14, 2018

Contact

Consumers

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Media

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Announcement

Apotex Corp. is voluntarily recalling **36 lots of Piperacillin and Tazobactam for Injection, USP 3.375 gram/vial and 4.5 gram/vial strengths,** to the consumer/user level. The Piperacillin and Tazobactam for Injection have been found to contain elevated levels of impurities that may result in decreased potency. The affected product is manufactured by Hospira Inc., a Pfizer Company and distributed in the US market by Apotex Corp.

Risk Statement: The decreased potency of Piperacillin and Tazobactam could result in worsening of the infection under treatment and under extreme circumstances lead to serious morbidities depending upon the severity of the illness. Elevated levels of impurities may result in various toxicities, such as liver, renal, and hematological toxicities. There have not been any reports of adverse events related to this recall to date.

Piperacillin and tazobactam for injection is a combination penicillin-class antibacterial and β- lactamase inhibitor, which can be used in adults and children 2 months and older and indicated for treatment of: Intra-abdominal infections, Skin and skin structure infections, Female pelvic infections, Community-acquired pneumonia and Hospital Acquired pneumonia. The Piperacillin and Tazobactam for Injection, USP vials are packaged in a Carton containing 10 single use vials. The affected Piperacillin and Tazobactam for Injection, USP 3.375 gram/vial and 4.5 gram/vial lots include the following and can be identified by NDC numbers stated on the Carton and on the single use vial:

Vial NDC	Carton NDC	Lot Number	Expiration Date	Strength	Configuration/Count
60505-0687-	60505-0687-4	501G014	05 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G015	09 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G016	10 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G017	10 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G018	10 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G019	10 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G020	10 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G021	10 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G022	10 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G023	10 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G024	11 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G025	11 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G026	11 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G027	11 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G028	11 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G029	11 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501G030	11 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H001	12 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H002	12 2018	3.375 gram/vial	Carton containing 10 Single Use Vials

Vial NDC	Carton NDC	Lot Number	Expiration Date	Strength	Configuration/Count
60505-0687-	60505-0687-4	501H003	12 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H004	12 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H005	12 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H006	12 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H007	12 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H008	12 2018	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H009	04 2019	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H012	06 2019	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H013	06 2019	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H018	09 2019	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0687-	60505-0687-4	501H019	09 2019	3.375 gram/vial	Carton containing 10 Single Use Vials
60505-0688-	60505-0688-4	502H001	01 2019	4.5 gram/vial	Carton containing 10 Single Use Vials
60505-0688-	60505-0688-4	502H003	04 2019	4.5 gram/vial	Carton containing 10 Single Use Vials
60505-0688-	60505-0688-4	502H004	04 2019	4.5 gram/vial	Carton containing 10 Single Use Vials
60505-0688-	60505-0688-4	502H005	04 2019	4.5 gram/vial	Carton containing 10 Single Use Vials
60505-0688-	60505-0688-4	502H009	05 2019	4.5 gram/vial	Carton containing 10 Single Use Vials
60505-0688-	60505-0688-4	502H012	05 2019	4.5 gram/vial	Carton containing 10 Single Use Vials

The affected Piperacillin and Tazobactam for Injection, USP 3.375 gram/vial and 4.5 gram/vial strengths were distributed Nationwide to wholesalers and one distributor.

Apotex Corp. has notified wholesalers/distributor by recall letter to arrange for return of any recalled product.

Wholesalers/retailers/hospitals/institutions with an existing inventory of the lots subject to this recall should stop use and distribution of the remaining units and quarantine immediately. Healthcare Professionals in your organization should be informed of this recall. If you have further distributed the recalled product, to the wholesale or retail level, please notify any accounts or additional locations which may have received the recalled product from you. For additional assistance, call GENCO Pharmaceutical Services, a subsidiary of FedEx Supply Chain (GENCO) at 1-877-319-8966 (7:00am – 5:00pm, CST Monday thru Friday), to arrange for their return.

Customers with questions regarding this recall can contact Apotex Corp. by phone-number 1- 800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday)or email address **UScustomerservice@Apotex.com. (mailto:UScustomerservice@Apotex.com)** Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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