

The United States: 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

The US Food and Drug Administration (FDA) announces that 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. 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:

Strength	Lot Number	Expiration Date
3.375 gram/vial	501G014	05 2018
	501G015	09 2018
	501G016, 501G017, 501G018, 501G019, 501G020, 501G021, 501G022, 501G023	10 2018
	501G024, 501G025, 501G026, 501G027, 501G028, 501G029, 501G030	11 2018
	501H001, 501H002, 501H003, 501H004, 501H005, 501H006, 501H007, 501H008	12 2018
	501H009	04 2019
	501H012, 501H013	06 2019
	501H018, 501H019	09 2019
4.5 gram/vial	502H001	01 2019
	502H003, 502H004, 502H005	04 2019
	502H009, 502H012	05 2019

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.

Please refer to the following website in FDA for details:

<https://www.fda.gov/Safety/Recalls/ucm607653.htm>

In Hong Kong, DBL Piperacillin and Tazobactam For Inj 4.5g (HK-59114) is a pharmaceutical product registered by Pfizer Corporation Hong Kong Limited (Pfizer), and is a prescription-only medicine. As confirmed by Pfizer, the affected batches have not been imported into Hong Kong. There is no piperacillin and tazobactam product of 3.375g strength registered in Hong Kong.

Ends/Tuesday, May 15, 2018

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