

Important Safety Information on the Recall of Mylan Piperacillin-Tazobactam for Injection, 3 g/0.375 g and 4 g/0.5 g Which May Contain Particulate Matter

June 24, 2015

Audience

Health care professionals working in hospitals and clinics

Please distribute to relevant Departments: Pharmacy, Paediatrics, Geriatrics, Internal Medicine, Nursing, Intensive Care and/or other Departments as required, affiliated clinics and other involved professional staff and **post this notice** in your institution.

Key messages

- A recall has been initiated for one (1) lot (lot 7103985) of Piperacillin-Tazobactam for Injection, 3 g/0.375 g and one (1) lot (lot 7103921) of Piperacillin-Tazobactam for Injection, 4 g/0.5 g by Mylan Pharmaceuticals ULC, due to the potential presence of particulate matter.
- If infused, particulate matter could potentially lead to patient harm including phlebitis and thrombo-embolism, which could result in death.
- Vials of the affected lot should not be used and should be returned as outlined in the Recall Notice issued by Mylan on June 23, 2015. Health care professionals are advised to remain vigilant in their follow up with patients who have been administered the impacted lots.

What is the issue?

Mylan Pharmaceuticals ULC has initiated a recall due to the potential presence of particulate matter in vials from affected lots of Piperacillin-Tazobactam for Injection (see table below).

The presence of particulate matter could pose the following risks, if injected: local inflammation, phlebitis, allergic response and/or embolization in the body and infection.

Products affected

The products impacted are:

<u>Product</u>	<u>DIN No.</u>	<u>Lot No.</u>	<u>Distribution Date</u>	<u>Exp. Date</u>
Mylan-Piperacillin and Tazobactam for Injection 3 g/ 0.375 g	02391538	7103985	Aug.27, 2014	Feb. 2016
AJ-Pip/Taz (Piperacillin and Tazobactam for Injection) 4 g/ 0.5 g	02391546	7103921	Dec. 1, 2014	Nov. 2015

Background information

Piperacillin-Tazobactam for Injection is indicated for the treatment of systemic and/or local bacterial infections caused by piperacillin-resistant, piperacillin/tazobactam susceptible, β -lactamase-producing strains.

The recent inspection of retention samples of two lots (lots 7103985 and 7103921) of Piperacillin-Tazobactam (3 g/ 0.375 g, and 4 g/ 0.5 g, respectively) revealed the presence of particulate matter in some of the vials inspected. These are the only lots within expiry distributed by Mylan Pharmaceuticals ULC to the Canadian market to date.

The two (2) affected lots of Piperacillin-Tazobactam (3 g/ 0.375 g and 4 g/ 0.5 g) for injection are being recalled.

The root cause of this issue is currently under investigation by Mylan Pharmaceuticals. No complaints or adverse event reports have been received in relation to this product from these lots.

Information for consumers

Consumers should contact their health care professional for more information.

Information for health care professionals

Vials of the affected lots of Piperacillin-Tazobactam should not be used and should be returned as outlined in the Recall Notice issued by Mylan on June 23, 2015.

Please inform other health care professionals in your organization of this recall notification. Health care professionals should also notify affiliated staff administering this product in a clinic setting.

If your institution or pharmacy has distributed the affected product lots further, notify recipients that they may have received the product lots identified above and ask them to return the affected product as indicated in the Recall Notice.

Action taken by Health Canada

Health Canada is communicating this important safety information to health care professionals and to the public through its MedEffect Canada website. Health Canada is also monitoring the recalls and the implementation of necessary corrective and preventive actions.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious local inflammation, phlebitis, allergic response and/or embolization in the body or other serious or unexpected infection or unexpected side effects in patients receiving Piperacillin-Tazobactam for Injection 3 g/0.375 g, and 4 g/0.5 g, respectively, should be reported to Mylan Pharmaceuticals ULC or Health Canada.

Mylan Pharmaceuticals ULC

85 Advance Road
Etobicoke, ON M8Z 2S6
1-800-575-1379

To correct your mailing address or fax number, contact Mylan Pharmaceuticals ULC

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, contact Health Canada at:

Health Products and Food Branch Inspectorate (HPFBI)

E-mail: DCVIU_UVCEM@hc-sc.gc.ca

Telephone: 1-800-237-9675

Fax: 1-613-946-5636



Original signed by

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