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# Health Product InfoWatch

July 2015

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## REPORTING ADVERSE REACTIONS

Canada Vigilance Program

Telephone: 1-866-234-2345

Fax: 1-866-678-6789

Online: [www.health.gc.ca/medeffect](http://www.health.gc.ca/medeffect)

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## HEALTH PRODUCTS MENTIONED IN THIS ISSUE

### Pharmaceuticals and Biologics

AJ-PIP/TAZ (piperacillin and tazobactam) for Injection  
Allerject (epinephrine)  
Baxter Clinimix (5% Travasol Amino Acid Injection Without Electrolytes in 16.6% Dextrose Injection)  
Forxiga (dapagliflozin)  
Invokana (canagliflozin)  
Methylprednisolone, Intravenous  
Mylan Piperacillin-Tazobactam for Injection  
Naturalyte Liquid Sodium Bicarbonate Concentrate  
SGLT2 Inhibitors (Forxiga and Invokana)  
Tecfidera (dimethyl fumarate)

### Other

Body Bentonite Unique Healing Powder  
DHEA 25  
Drugs from Hospira S.P.A.  
Promatrix DHEA 25  
Quarantined Health Products - Polydrug Laboratories  
Quarantined Health Products - Zhejiang Hisun Pharma  
Sport X Ephedrine  
Unauthorized Health Products - Better Bodies Supplements

This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as a selection of new health product safety information meant to raise awareness. New information contained in this issue is not comprehensive but rather represents a selection of clinically relevant items warranting enhanced dissemination.

Canada

## MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of [health product advisories](#) as well as [summaries of completed safety reviews](#) published in June 2015 by Health Canada.

### **AJ-PIP/TAZ (piperacillin and tazobactam) for Injection**

[Health Product Risk Communication](#)

Three lots of AJ-PIP/TAZ (piperacillin and tazobactam) for Injection, 4 g/0.5 g by Jamp Pharma Corporation were recalled due to the potential presence of particulate matter.

### **Allerject (epinephrine)**

[Advisory](#)

Two lots of Allerject (0.15 mg/0.15 mL auto-injector) were recalled due to a manufacturing defect with the needle. As a result, the device may not deliver the epinephrine.

### **Baxter Clinimix, 5% Travasol Amino Acid Injection Without Electrolytes in 16.6% Dextrose Injection**

[Health Product Risk Communication](#)

Baxter recalled 3 lots of Clinimix, 5% Travasol Amino Acid Injection Without Electrolytes in 16.6% Dextrose Injection 1L due to particulate matter found in the solution.

### **Body Bentonite Unique Healing Powder by Donna Pessin**

[Foreign Product Alert](#)

Health Canada advised Canadians not to use this foreign health product as it was found to contain high levels of metals, which may pose serious health risks. This product is not authorized for sale in Canada and has not been found in the Canadian marketplace but it is possible it may have been brought in the country by travellers or purchased over the Internet.

### **Drugs from Hospira S.P.A.**

[Information Update](#)

Health Canada is restricting the importation of drugs from Hospira S.P.A. in Liscate, Italy, due to data integrity concerns. This measure was taken to help mitigate any potential risk in light of recent findings that raised concerns about the reliability of the laboratory data generated at this site. Health Canada has compiled a list of marketed products affected by the importation restrictions and will update it as new information becomes available.

**Methylprednisolone,  
Intravenous**

Summary Safety Review

This safety review was initiated following the identification of 28 published international cases of liver injury associated with intravenous methylprednisolone. Health Canada concluded there was evidence of an association between intravenous methylprednisolone and the occurrence of liver injury with a variable time to onset. The Canadian prescribing information for Solu-Medrol and Solu-Medrol Act-O-Vials has been updated to better reflect the available evidence regarding the risk of liver injury. Manufacturers of generic versions will also update their product information.

**Mylan Piperacillin-  
Tazobactam for Injection**

Health Product Risk  
Communication

One lot of Piperacillin-Tazobactam for Injection, 3 g/0.375 g and one lot of Piperacillin-Tazobactam for Injection, 4 g/0.5 g were recalled by Mylan Pharmaceuticals ULC, due to the potential presence of particulate matter.

**NaturaLyte Liquid Sodium  
Bicarbonate Concentrate**

Health Product Risk  
Communication

One bottle of NaturaLyte Liquid Bicarbonate Concentrate from a lot which was not distributed in Canada had bacterial contamination. The possibility that other lots manufactured in 2015 may be affected cannot be excluded.

**Quarantined Health  
Products - Polydrug  
Laboratories**

Information Update

Health Canada has requested that Canadian importers voluntarily quarantine drug products with active pharmaceutical ingredients (APIs) manufactured or tested by Polydrug Laboratories, in Ambarnath, Maharashtra, India, due to data integrity concerns.

**Quarantined Health  
Products - Zhejiang Hisun  
Pharma**

Information Update

Health Canada has requested that Canadian importers voluntarily quarantine drug products with active pharmaceutical ingredients (APIs) manufactured or tested by Zhejiang Hisun Pharma Company Ltd., in Zhejiang, China, due to data integrity concerns.

**SGLT2 Inhibitors Forxiga  
and Invokana**

Information Update

Health Canada initiated a safety review for the prescription diabetes drugs dapagliflozin (Forxiga) and canagliflozin (Invokana) and the risk of ketoacidosis. Health Canada will review the available information and will determine whether changes are needed in the prescribing information for this class of drug.

## **Sport X Ephedrine, DHEA 25 and Promatrix DHEA 25**

Advisory

Three unauthorized health products that may pose serious risks to the health of Canadians were seized by Health Canada. The products “Sport X Ephedrine”, “DHEA 25” and “Promatrix DHEA 25” were being sold by S&H Health foods on Burnhamthorpe Rd. W., in Mississauga.

## **Tecfidera (dimethyl fumarate)**

Summary Safety Review

This safety review evaluated the potential risk of hypersensitivity reactions associated with Tecfidera (dimethyl fumarate). Health Canada concluded that the overall benefits of Tecfidera continue to outweigh the risks when used as recommended. The Canadian prescribing information for Tecfidera was updated to provide information concerning hypersensitivity reactions, including angioedema and anaphylaxis, as well as severe flushing reactions.

## **Unauthorized Health Products from Better Bodies Supplements**

Advisory

Health Canada informed Canadians that 8 unauthorized health products were seized from Better Bodies Supplements on Main Street North, in Airdrie, Alberta. These products were also available for purchase from the retailer’s online store “Better Bodies Nutrition”. These products contain a combination of ingredients (synephrine/ephedrine/ephedra, caffeine and L-dopa) that can cause serious health risks.

## **HELPFUL LINKS**

- [MedEffect™ Canada](#)
- [Recalls and Safety Alerts Database](#)
- [Summary Safety Reviews](#)
- [Canada Vigilance Adverse Reaction Online Database](#)
- [Drug Product Database](#)
- [Canadian Drug Shortage Database](#)
- [The Drug and Health Product Register](#)

## **Suggestions?**

Your comments are important to us. Let us know what you think by reaching us at [InfoWatch\\_InfoVigilance@hc-sc.gc.ca](mailto:InfoWatch_InfoVigilance@hc-sc.gc.ca)

Health Canada  
Marketed Health Products Directorate  
Address Locator 0701D  
Ottawa ON K1A 0K9  
Telephone: 613-954-6522  
Fax: 613-952-7738

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*Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.*

*Due to time constraints relating to the production of this publication, information published may not reflect the most current information.*

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