Important Safety Information on SOLU-MEDROL ACT-O-VIAL 40 mg – Risk of Hypersensitivity in Individuals Allergic to Cow's Milk

2017/09/06

Audience
Healthcare professionals including physicians, pharmacists and nurses

Key messages

- **SOLU-MEDROL ACT-O-VIAL 40 mg is the only formulation of methylprednisolone in Canada that contains bovine-sourced lactose as an excipient.**
- **Serious allergic reactions, including bronchospasm and anaphylaxis have been reported in patients allergic to cow's milk proteins who were treated intravenously or intramuscularly with SOLU-MEDROL ACT-O-VIAL 40 mg.**
- **Healthcare professionals are reminded that:**
    - **SOLU-MEDROL ACT-O-VIAL 40 mg is contraindicated in patients with a known or suspected hypersensitivity to cow's milk.**
    - **The administration of SOLU-MEDROL ACT-O-VIAL 40 mg should be stopped, and the patient should be treated accordingly if their existing symptoms worsen or new allergic symptoms occur during treatment.**
    - **Alternative treatments, including the use of corticosteroid formulations that do not contain bovine-sourced ingredients, should be considered for acute allergy management in patients allergic to cow's milk proteins as SOLU-MEDROL ACT-O-VIAL 40 mg has the potential to exacerbate the condition.**
- **The Canadian Product Monograph has been updated to reflect this new safety information.**

What is the issue?
Severe hypersensitivity reactions following the use of methylprednisolone sodium succinate for injection products containing lactose were internationally reported in the post-marketing setting in patients hypersensitive to milk. SOLU-MEDROL ACT-O-VIAL 40 mg, the only formulation of SOLU-MEDROL in Canada that contains bovine-sourced lactose as an excipient, should not be used in patients with a known or suspected hypersensitivity to cow's milk or its components or other dairy products.

To date, no Canadian cases of hypersensitivity related to SOLU-MEDROL ACT-O-VIAL 40 mg treatment have been identified.

Products affected
Pfizer Canada SOLU-MEDROL ACT-O-VIAL (methylprednisolone sodium succinate for injection) 40 mg.

Background information
Intravenous administration of SOLU-MEDROL (methylprednisolone sodium succinate) is indicated in situations in which a rapid and intense hormonal effect is required. These include the treatment of various conditions such as allergic reactions or inflammation. In some conditions, it may be administered by slow intravenous or intramuscular administration when used as adjunctive therapy for treatment of various conditions such as acute systemic lupus erythematosus, acute rheumatic fever, and acute gout. In Canada, SOLU-MEDROL is available in 500 mg or 1 g PLAIN VIALS or in 40 mg, 125 mg, 500 mg and 1 g ACT-O-VIALS. The only difference between them is that the ACT-O-VIALS are packaged together with the diluent, whereas the PLAIN VIALS are not. SOLU-MEDROL ACT-O-VIAL 40-mg is the only formulation in Canada that contains bovine-sourced lactose as an excipient.

International cases of hypersensitivity to methylprednisolone in patients with a milk allergy have been described in the medical literature and reported to Pfizer Canada Inc. In a very small number of cases, patients who were hypersensitive to milk developed severe hypersensitivity reactions following the use of methylprednisolone sodium succinate which contained lactose. Hypersensitivity to milk is distinct from intolerance to lactose-containing foods. Lactose intolerance is a non-immunologically mediated reaction to milk caused by a lack of the enzyme lactase in the small intestine, which converts lactose into glucose and galactose. To date, no Canadian cases of hypersensitivity related to SOLU-MEDROL ACT-O-VIAL 40 mg treatment have been identified.

In October 2016, Health Canada published an article in the *Health Product InfoWatch* (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch/health-product-infowatch-october-2016.html) to increase awareness among healthcare professionals on this safety issue. The Canadian Product Monograph has recently been updated to indicate that SOLU-MEDROL ACT-O-VIAL 40 mg formulation is now contraindicated in patients with a known or suspected hypersensitivity to cow's milk or its

components or other dairy products because it may contain trace amounts of milk proteins.

Information for consumers
SOLU-MEDROL is a prescription medicine used to reduce symptoms such as swelling and redness, to decrease the body's immune response to certain diseases, or in the treatment of allergic reactions. It is administered intravenously or intramuscularly by a healthcare professional.

SOLU-MEDROL Act-O-Vial 40 mg is the only formulation of SOLU-MEDROL in Canada that contains a non-medicinal ingredient called lactose produced from cow's milk. The lactose from cow's milk may contain trace amounts of protein that can cause a hypersensitivity reaction (a reaction of the immune system) in individuals who are allergic to cow's milk protein. In rare cases, patients who were allergic to milk developed a severe hypersensitivity reaction following the use of SOLU-MEDROL Act-o-Vial 40 mg.

Cow's milk allergy and lactose intolerance are not the same. Lactose intolerance does not involve an immune system reaction. It is caused by lack of lactase, an enzyme that is needed to digest lactose, the sugar in milk.

Patients should inform their healthcare professional if they have a known or suspected hypersensitivity to cow's milk before starting SOLU-MEDROL Act-O-Vial 40 mg treatment.

Information for health care professionals
Healthcare professionals are reminded that:

- SOLU-MEDROL ACT-O-VIAL 40 mg is the only formulation of SOLU-MEDROL in Canada that contains bovine-sourced lactose as an excipient. It is contraindicated in patients with a known or suspected hypersensitivity to cow's milk.

- If a patient has signs or symptoms of hypersensitivity following administration of SOLU-MEDROL ACT-O-VIAL 40 mg, administration should be stopped, and the patient should be treated accordingly.

- In the treatment of acute allergic conditions, the use of corticosteroids which do not contain lactose from animal sources should be considered if appropriate, as the use of SOLU-MEDROL ACT-O-VIAL 40 mg for injection in individuals with hypersensitivity to milk proteins may exacerbate the condition.

Action taken by Health Canada
Health Canada has worked with the manufacturer to update the Canadian Product Monograph to include this safety information.

Health Canada is communicating this important safety information to healthcare professionals via the Recalls and Safety Alerts Database on the Healthy Canadians

Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of hypersensitivity or other serious or unexpected side effects in patients receiving SOLU-MEDROL ACT-O-VIAL 40 mg should be reported to Pfizer Canada Inc. or Health Canada.

Pfizer Canada Inc. Contact Information
17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5
Telephone: If you have an inquiry of a medical nature related to SOLU-MEDROL, please contact our Medical Information Group at 1-800-463-6001. For all other inquiries, please contact our Customer Service Group at 1-800-387-4974.

To report an adverse event (or suspected side-effect) experienced with a Pfizer medication (prescription, non-prescription or a vaccine) please contact Pfizer at 1-866-723-7111 or by fax at 1-855-242-5652.

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) 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:
Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone:613-954-6522
Fax:613-952-7738

Please refer to the Pfizer Canada SOLU-MEDROL Product Monograph on pfizer.ca for further information.

Sincerely,

Vratislav Hadrava M.D., Ph.D.
Vice-President and Medical Director
Pfizer Canada Inc.