

Healthy Canadians

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Solu-Cortef (hydrocortisone sodium succinate for injection) 100 mg/2 mL single-dose Act-O-Vial - Recalled Lots due to Potential for Dosing Error

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Starting date: August 2, 2016
Posting date: August 2, 2016
Type of communication: Dear Healthcare Professional Letter
Subcategory: Drugs
Source of recall: Health Canada
Issue: Important Safety Information
Audience: Healthcare Professionals, General Public
Identification number: RA-59664

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Audience

Healthcare professionals including physicians, pharmacists and nurses.

Please distribute this communication to the appropriate personnel within your facility who are using this product.

Key messages

- **Pfizer is recalling 8 lots of Solu-Cortef (hydrocortisone sodium succinate for injection) 100 mg/2 mL single-dose Act-O-Vial as a result of a labelling text error on the side panel of the carton which indicates that the reconstituted product contains 125 mg /mL hydrocortisone instead of 50 mg/mL. This could lead to a potential dosing error.**
- **Solu-Cortef 250 mg/2mL or 500mg/4mL Act-O-vials (single use) can be used as alternatives however, healthcare professionals need to be aware that the alternative products have a reconstituted concentration of 125 mg/mL. Changes to the volume for dosing will be required (see Information for Healthcare Professionals below).**
- **Solu-Cortef should be reserved for emergency use only until the shortage situation has been resolved. Therapeutic alternatives should be considered for non-urgent medical uses.**
- **Healthcare professionals should inform and instruct patients on how to appropriately use the correct volume of the alternate vial strength of Solu-Cortef or any alternative product.**

Issue

Solu-Cortef (hydrocortisone sodium succinate for injection) 100 mg /2 mL single-dose Act-O-Vial has a labelling text error on the side panel of the carton. It indicates that the reconstituted product contains **125 mg/mL hydrocortisone instead of 50 mg/mL** (see visual below).

This labelling error on the carton has resulted in a product recall which in turn has generated a supply shortage of Solu-Cortef (hydrocortisone sodium succinate for injection) 100 mg/2 mL single-dose Act-O-Vial. During the temporary shortage, the use of the 250 mg/2 mL or the 500 mg/4 mL Solu-Cortef Act-O-Vials (with appropriate adjustment to the volume of the dose), or alternate products,1 should be considered.

The concentration displayed on the front panel of the carton, the vial label and the product leaflets are all correct.

Products affected

Solu-Cortef (hydrocortisone sodium succinate for injection) 100 mg/2 mL single-dose Act-O-Vial sterile powder and diluent, DIN 00030600, supplied in packages of 10 vials. Please see below for the information on the impacted product lots:

Impacted product lots

PRODUCT DESCRIPTION	DIN	SIZE	Product Code	UPC CODE	LOT #
Solu-CORTEF® 100 mg single-dose ACT-O-VIAL	00030600	10x2 mL (AOV)	52240	621027 522407	L42719, L58373, L58374, M41003, M63458, N15764, N54056, N62805

Background information

Solu-Cortef for injection is indicated for the treatment of multiple diseases, disorders and medical conditions, including medical emergencies such as shock secondary to adrenocortical insufficiency. This product may be administered by intravenous injection, intravenous infusion, or by intramuscular injection, the preferred method for initial emergency use being intravenous injection.

Re-supply of Solu-Cortef 100 mg / 2mL is currently expected the week of August 22, 2016.

Who is affected

Advice for Consumers

Patients should consult with their healthcare professional to confirm that they are receiving the correct dose of their medication. Patients with questions about their supply or about treatment options during the shortage period should talk to their healthcare professional.

Information for health care professionals

Solu-Cortef should be reserved for emergency use only until the shortage situation has been resolved. Healthcare professionals are encouraged to consider other therapeutic alternatives for any non-urgent medical use of Solu-Cortef.

If the 250 mg and 500 mg Solu-Cortef vials are used, please follow the instructions to adjust the injection volume as per the table below:

Instructions

Required dose	Solu-Cortef 100 mg Act-O-vials (single use) (50 mg per mL) Volume of injection	Solu-Cortef 250 mg or 500 mg Act-O-vials (single use) (125 mg per mL) Volume of injection
100 mg	2 mL	0.8 mL

Healthcare professionals should inform and instruct patients on how to appropriately use the correct volume of the alternate vial strength of Solu-Cortef or of the alternative therapeutic product.

Action taken by Health Canada

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. Health Canada is also monitoring the recall and the implementation of necessary corrective and preventive actions.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of dosing error or other serious or unexpected side effects in patients receiving Solu-Cortef 100 mg/ 2mL should be reported to Pfizer Canada Inc. or Health Canada.

Pfizer Canada Inc.

17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5

Telephone: If you have an inquiry of a medical nature related to Solu-Cortef® (hydrocortisone sodium succinate for injection) 100 mg / 2mL single-dose Act-o-Vial, 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](#) 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:

Regulatory Operations and Regions Branch
E-mail: dcviu_uvcem@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-563

Sincerely,

Original signed by

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

Reference

8/5/2016 Solu-Cortef (hydrocortisone sodium succinate for injection) 100 mg/2 mL single-dose Act-O-Vial - Recalled Lots due to Potential for Dosing Error - Recall...

1 Bornstein SR, Allolio B, Arlt W, et al. Diagnosis and treatment of primary adrenal insufficiency: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2016;101(2):364-89.

Images

Select thumbnail to enlarge



For more information

The manufacturer advised Health Canada of the risk associated with this health product. Health Canada supports the actions taken by the manufacturer and as such a risk assessment was not required and a Summary Safety Review was not prepared.

Date modified: 2016-08-02