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

2016/08/02

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/4mLAct-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.**

What is the 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:

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.

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 Healthcare 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:

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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php)

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,

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

Reference

[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.

GLUCOCORTICOID / GLUCOCORTICOÏDE

Each Act-O-Vial† contains: / Une fiole Act-O-Vial† contient :

Powder / Poudre

Hydrocortisone (as sodium succinate)	100 mg	hydrocortisone (sous forme de succinate sodique)
Monobasic sodium phosphate anhydrous	0.8 mg	phosphate monobasique de sodium anhydre
Dibasic sodium phosphate dried	8.73 mg	phosphate dibasique de sodium sec

Diluent / Diluant

Sterile Water for Injection	q.s.	eau stérile pour injection

After reconstitution each Act-O-Vial† delivers 2 mL containing 100 mg hydrocortisone (as sodium succinate). Each mL contains: 125 mg hydrocortisone.

Après la reconstitution de la solution, une fiole Act-O-Vial† fournit 2 mL contenant 100 mg d'hydrocortisone (sous forme de succinate sodique) Un mL contient : 125 mg d'hydrocortisone.

Usual Adult Dose: See Product Monograph for complete dosage, administration and direction for use.

Posologie habituelle – Adulte : Voir la monographie du produit pour connaître la posologie, les directives d'administration et le mode d'emploi.