Important Safety Information on Alveda Furosemide Injection USP 10 mg/mL Recall of One (1) Lot Due to the Same Barcode as Alveda Epinephrine Injection USP 1 mg/mL

05/22/2015

Audience

Physicians, Hospitals, Hospital Pharmacists, Long Term Care Facilities, Paramedics/Emergency Services, Retail Pharmacies, Medical Clinics and Dentists.

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

Key messages

- One lot (lot number: 30208) of Furosemide Injection USP 10 mg/mL (DIN 02384094) marketed and sold by Alveda Pharmaceuticals Inc. is being recalled, due to an incorrect barcode on the ampoule label. The barcode reads (01)00837641000591 which is the same barcode as on the ampoule label of Alveda Epinephrine Injection USP 1 mg/mL (DIN 02325225). Epinephrine is not being recalled so as not to precipitate a shortage.

- If your facility uses a barcode system, this could result in the potential for Alveda Furosemide Injection USP 10 mg/mL to be mistaken for Alveda Epinephrine Injection USP 1 mg/mL or Alveda Epinephrine Injection USP 1 mg/mL to be mistaken for Alveda Furosemide Injection USP 10 mg/mL.

- Ampoules of Furosemide Injection USP 10 mg/mL (Lot number:30208) should be returned as outlined in the Recall Notice issued by Alveda Pharmaceuticals Inc. on May 22, 2015.

- Check inventory of Alveda Epinephrine Injection USP 1 mg/mL in all locations of your facility, including crash carts, and ensure that it is stocked correctly. The name of the product on the inner label should be verified against the ampoule barcode to ensure that Alveda Epinephrine Injection is correctly identified in your barcode and inventory management systems and take corrective action if necessary.

- Also check your current inventory to ensure there is no Alveda Epinephrine USP 1 mg/mL Injection stocked as Furosemide Injection.

What is the issue?

Alveda is recalling one lot of its Furosemide Injection USP 10 mg/mL which has the same barcode on its inner label as that of its Epinephrine Injection USP 1 mg/mL and could result in a serious medication error due to misidentification of either product leading to inadvertent administration of the wrong product.

Aside from the barcode, the active ingredient, declared strength and all other label details are correct on each of the inner labels of Alveda Furosemide Injection USP 10 mg/mL and Alveda Epinephrine Injection USP 1mg/mL.

Products affected

Recalled Product:

Product	DIN	Lot	Expiry date	Date of distribution
Furosemide Injection USP 10 mg/mL	02384094	30208	2016.07	2013.11.13

Background information

Furosemide Injection USP is indicated when a rapid onset and intense diuresis is desired, e.g. acute pulmonary edema, cerebral edema.

Epinephrine Injection USP is used along with emergency medical treatment to treat life-threatening allergic reactions caused by insect bites or stings, foods, medications and other causes. It is also used in cardiac arrest and to prolong the action of infiltration anaesthetics.

Information for consumers

Consumers should consult their health care professional if they require more information.

Information for health care professionals

Ampoules of the affected lot of Furosemide should not be used and should be returned as outlined in the Recall Notice issued by Alveda Pharmaceuticals Inc. on May 22, 2015.

Institutions and pharmacies should check inventory of Alveda Epinephrine Injection USP 1 mg/mL (DIN 02325225) in all locations of your facility, including crash carts, and ensure that it is stocked correctly. The name of the product on the inner label should be verified against the ampoule barcode to ensure that Alveda Epinephrine Injection 1 mg/mL is correctly identified in your barcode and inventory management systems.

Also check your current inventory to ensure there is no Alveda Epinephrine USP 1 mg/mL Injection stocked as Furosemide Injection.

Please inform other health care professionals in your organization of this recall. If your institution or pharmacy has distributed the affected product lot further, notify recipients that they may have received the product lot identified above and ask them to return the affected product as indicated in the Recall Notice.

To correct this error, a new barcode system has been implemented. The barcodes for both products have been revised and all future lots will have a distinct product-specific barcode associated with each product. Hospitals, Institutions and pharmacies are advised to prepare for the possibility of a transition period where there is the potential for two different bar codes to be associated with the same product (DIN).

This Risk Communication will be included in all shipments until the problem is resolved.

Action taken by Health Canada

Health Canada is communicating this important safety information to healthcare professionals and to the public through its MedEffect Canada website. 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 medication error or other serious or unexpected side effects in patients receiving Furosemide Injection USP 10 mg/mL or Epinephrine Injection USP 1 mg/mL should be reported to Alveda Pharmaceuticals Inc. or Health Canada.

Alveda Pharmaceuticals Inc.
21 St. Clair Avenue East, Suite 1100
Toronto, Ontario
M4T 1L9
1-800-656-0793
drugsafety@alvedapharma.com

To correct your mailing address or fax number, contact Alveda Pharmaceuticals Inc.

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 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
E-mail: DCVIU_UVCEM@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

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Senior Manager of Quality

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