Important Safety Information on Alveda Atropine Injection BP 0.4 mg/mL Recall of One (1) Lot Due to the Same Barcode as Alveda Epinephrine Injection USP 1 mg/mL

20/11/2015

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: 50187) of Atropine Injection BP 0.4 mg/mL (DIN 02094681) 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 number on the ampoule label of Alveda Epinephrine Injection USP 1 mg/mL (DIN 02325225).**
- **If your facility uses a barcode system, this could result in the potential for Alveda Atropine Injection BP 0.4 mg/mL being mistaken for Alveda Epinephrine Injection USP 1 mg/mL or Alveda Epinephrine Injection USP 1 mg/mL being mistaken for Atropine Injection BP 0.4 mg/mL. This could result in serious patient harm.**
- **Check current inventory to ensure there is no Alveda Atropine Injection BP 0.4 mg/mL stocked as Alveda Epinephrine Injection USP 1 mg/mL.**
- **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.**
- **Ampoules of Alveda Atropine Injection BP 0.4 mg/mL (lot number: 50187) should be returned as outlined in the Recall Notice issued by Alveda Pharmaceuticals Inc. on November 19, 2015.**

What is the issue?

Alveda is recalling one lot of its Atropine Injection BP 0.4 mg/mL which has the

same barcode on the ampoule 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 Atropine Injection BP 0.4 mg/mL and Alveda Epinephrine Injection USP 1mg/mL.

Products affected

Recalled Product:				
Product	**DIN**	**Lot**	**Expiry date**	**Date of distribution**
Alveda Atropine Injection BP 0.4 mg/mL	02094681	50187	2019.04	Since 2015.08.13

Background information

Atropine Injection BP 0.4 mg/mL is indicated for reduction of secretions of the respiratory tract before anesthesia, prevention and treatment of bradycardia caused by excessive vagal stimulation. It is also an antidote for cholinesterase inhibitors and for poisoning from muscarinic mushrooms or organophosphates.

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 Alveda Atropine Injection BP 0.4 mg/mL should not be used and should be returned as outlined in the Recall Notice issued by Alveda Pharmaceuticals Inc. on November 19, 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 Atropine Injection.

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

To correct this error, a new barcode system has been implemented by Alveda. The barcode for both products have been revised and all future lots will have the new barcode associated to each product.

Action taken by Health Canada

Health Canada is communicating this important safety information to health care professionals and to the public through its Healthy Canadians Web site (www.healthycanadians.gc.ca) and MedEffect™ e-Notice. 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 health care professionals and consumers reporting them. Any case of medication error or other serious or unexpected side effects in patients receiving Atropine Injection BP 0.4 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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