April 09, 2013

URGENT DRUG RECALL (UPDATE)

Apotex is updating all direct account **Wholesalers, Distributors, and Retailers** that have received the impacted lot below. The recall has been reclassified by Health Canada's Therapeutic Products Directorate as a voluntary TYPE I & TYPE II recall being conducted up to the **Retail level and to a subset of the population**. This product is manufactured by a third party and distributed by Apotex. This voluntary TYPE I & TYPE II recall is being conducted in coordination with the Health Products Food Branch Inspectorate Canada. **Other lots or products are not impacted by this recall.**

Product Name	DIN	Strength	PKG Format	UPC Code	LOT Number	EXP. Date
ALYSENA™ 28 (Levonorgestrel and Ethinyl Estradiol Tablets USP)	02387883	100 µg / 20µg	28 x 1 BLS in a carton	771313219914	LF01899A	10/2014

RECALL RISK/CLASSIFICATION

- TYPE I: For patients which includes patients that should not get pregnant, whether for medical reasons or exposure to agents detrimental to a developing fetus (such as those on pregnancy prevention programmes while taking drugs that can cause harm to a developing fetus).
- TYPE II: General Population

REASON FOR MARKET ACTION

Product lot identified in this recall notification may contain two rows of placebo instead of one row (14 tablets instead of 7 tablets) and two rows of active contraceptive tablets (14 tablets instead of 21 tablets) in the blister pack.

HEALTH ASSESSMENT

Ingestion of only 14 tablets of active instead of intended 21 of oral contraceptive would most likely result in reduced efficacy for contraception and therefore possibility of unplanned pregnancy cannot be ruled out.

ACTIONS TO BE TAKEN

1. **Stop distributing and quarantine** above mentioned lot of ALYSENA™ 28 Tablets.

2. **Patients** who have received ALYSENA™ 28 lot LF01899A or have questions regarding this recall please contact your pharmacy. **Patients should not interrupt their therapy** but should consult their health care provider for appropriate medical advice.

3. **Retail and hospital pharmacies** that track lot numbers dispensed to patients please contact patients who have received ALYSENA™ 28 lot LF01899A, advise them of the recall, and recover any units of lot LF01899A for return.

   For retail and hospital pharmacies that are unable to confirm the lot number of ALYSENA™ 28 lot LF01899A dispensed to patients, please contact patients who have received ALYSENA™ 28 lot LF01899A between December 4th, 2012 and receipt of this notification, advise them of the recall, and recover any units of lot LF01899A for return.

4. **Wholesalers/ Distributors are to conduct a sub-recall** to retail customers to whom you have shipped the affected lot, by informing them of the recall, requesting that they remove the affected lot from sale and return the stock to the wholesaler from whom it was purchased. Your customers **should not** return stock directly back to Apotex or Stericycle.

5. **Customers who purchased the affected product DIRECTLY from Apotex**, you are requested to conduct a physical count of affected inventory on hand. Note: Wholesaler/Distributors must also include in their count, inventory that was returned by their retail customers.

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Record total inventory on hand on the Business Reply Form (BRF) included in this letter and fax to Stericycle to the Toll-Free fax number below. **Note:** If you have NO inventory on hand, you are still required to complete the BRF and fax it back to Stericycle documenting that no affected inventory is on hand.

6. **If this letter has been forwarded to a retail pharmacy or institution that has purchased affected inventory through a wholesaler/distributor:**

   The below mentioned return process **DOES NOT** apply to you. Retail customers, who purchased through a wholesaler/distributor, must return the affected inventory back to the establishment from where the inventory was purchased. For these retailers, please contact your Wholesaler for specific return and credit instructions**. DO NOT** return your affected inventory back to Apotex or Stericycle.

7. **Returning affected inventory to Stericycle. For customers who purchased affected product DIRECTLY from Apotex**, place all affected product in a shipping carton, enclose a hard copy of the completed BRF, identify the product as "Recall Product" on the outside of the shipper and apply the prepaid shipping label provided. Contact Stericycle for additional return labels if required.

Return address:

Event #: 8415
Stericycle Inc. 25 Ironside Crescent,
Toronto, Ontario M1X 1G5
Toll-free FAX: 1-866-324-3734

ADDITIONAL INFORMATION
For customers who purchased affected product DIRECTLY from Apotex, a credit will be issued for affected stock upon receipt of inventory at Stericycle.

Please complete and return by fax the enclosed Business Reply Form to receive prompt credit to your account. Also, please identify the returned merchandise as "RECALL PRODUCT" on the outside of the shipper.

If further assistance is required for returns please contact Stericycle at: **1-866-367-4537**

Sincerely,

Apotex