Urgent: Drug Recall

Levonorgestrel and Ethinyl Estradiol Tablets, USP

Recall initiated by the Distributor: Mylan Pharmaceuticals Inc.
Product Manufactured by: Mylan Laboratories Ltd, Ahmedabad

August 31, 2018

PRODUCT

NDC	Name and Strength	Batch #	Expires
0378-7281-53	Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.03 mg	8508F004A	February 2020

REASON

Mylan Pharmaceuticals Inc. is conducting a voluntary recall at the retail level of one batch of Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.03 mg. The product is packaged in a carton that contains 3 blister packs, each enclosed in a foil pouch. Each blister pack contains 91 tablets: 84 white tablets, each containing 0.15 mg of levonorgestrel and 0.03 mg of ethinyl estradiol and 7 green inert tablets. This batch was distributed in the US between July 16, 2018 and August 13, 2018.

This batch is being recalled due to the incorrect NDC and product name appearing on some blister packs. Some blister packs in this batch may incorrectly identify the NDC as 0378-7285-85, and the product name as Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg and Ethinyl Estradiol Tablets, USP 0.01 mg. The outer carton and foil pouches correctly identifies the product as Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.03 mg and bears the correct NDC.

No risk to patient safety is expected.

Levonorgestrel and ethinyl estradiol tablets are indicated for use by females of reproductive potential to prevent pregnancy.

ACTION

1. Immediately examine your inventory, quarantine and discontinue distribution of this batch.
2. In addition, if you have further distributed the recalled product, please identify your retail level customers and notify them at once of this product recall.
3. Additionally, Stericycle will notify your retail level customers that received the affected batch. Please provide a list of customers via Microsoft excel file to mylan8482@stericycle.com within 10 business days.
4. Carry out a physical count and record this data on the Business Reply Card and the Packing Slip which are included with this letter.
5. Mail the postage paid Business Reply Card to the address provided.
6. Return the product with the Packing Slip using the prepaid UPS Return Service shipping labels to:
   Stericycle
   Event # 8482
   2670 Executive Drive, Suite A
   Indianapolis, IN 46241

OTHER

This recall extends to the retail level.
Credit/check will be issued for return of recalled product only.
This recall is being conducted with the knowledge of the Food and Drug Administration.
For questions regarding the recall, please call Stericycle at 888-240-4291.
Normal business hours are Monday through Friday, 8AM to 5PM Eastern Standard Time.
Any other product returned that is not involved with this recall will be destroyed and credit will not be issued.

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.