From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, May 30, 2017 10:32 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Product Recall - Lupin Pharmaceuticals Inc.

Mibela 24 Fe Chewable Tablets by Lupin Pharmaceuticals Inc.: Recall - Out of Sequence Tablets and Missing Expiry/Lot Information

AUDIENCE: Family Practice, Health Professional, Pharmacy, Consumers

ISSUE: Lupin Pharmaceuticals Inc. announced a recall of lot L600518, Exp 05/18 of Mibelas 24 Fe (Norethindrone Acetate and Ethinyl Estradiol 1 mg/0.02 mg chewable and ferrous fumarate 75 mg) Tablets at the consumer level. A confirmed market compliant indicated a packaging error, where the blister was rotated 180 degrees within the wallet, reversing the weekly tablet orientation and making the lot number and expiration date no longer visible. The first four days of therapy would have had four non-hormonal placebo tablets as opposed to the active tablets.

As a result of this packaging error, oral contraceptive tablets that are taken out of sequence may place the user at risk for contraceptive failure and unintended pregnancy. The reversing the order may not be apparent to either new users or previous users of the product, increasing the likelihood of taking the tablets out of order. For patients in whom a pregnancy is contraindicated or in whom concomitant medication(s) may have teratogenic effects, an unintended pregnancy may cause significant adverse maternal or fetal health consequences, including death.To date there have been no reports of such adverse events.

BACKGROUND: This product is an oral contraceptive indicated for the prevention of pregnancy in women who elect to use oral contraceptives. These products are packaged in blister packs containing 28 tablets: 24 white to off-white tablets of active ingredients debossed with “LU” on one side and “N81” on the other; and 4 tablets of inert ingredients debossed with “LU” on one side and “M22” on the other side. This product was distributed Nationwide in the U.S.A. to wholesalers, clinics and retail pharmacies.

RECOMMENDATION: Consumers who have the affected product should notify their physician and return the product to the pharmacy or place of purchase and contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product.
Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Please see the complete MedWatch Safety Alert
at: https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm560908.htm

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

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