July 31, 2023

Lupin Pharmaceuticals issues voluntary nationwide recall of 2 lots of Tydemy (drospirenone, ethinyl estradiol and levomefolate calcium tablets 3 mg/0.03 mg/0.451 mg and levomefolate calcium tablets 0.451 mg) due to out of specification (OOS) results at the 12-month stability time point

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About this recall:

Lupin Pharmaceuticals (Lupin) is voluntarily recalling two lots of Tydemy (drospirenone, ethinyl estradiol and levomefolate calcium tablets 3 mg/0.03 mg/0.451 mg and levomefolate calcium tablets 0.451 mg) to the patient (consumer/user) level due to out-of-specification (OOS) test results at the 12-month stability time point. Specifically, one lot (L200183) tested low for ascorbic acid (an inactive ingredient) and high for a known impurity.

To date, Lupin has received no reports of adverse events related to the recalled batches. Regardless, Lupin is recalling these two batches because if there were a significant reduction in the amount of inactive content (ascorbic acid), this could potentially impact the effectiveness of the product, which could potentially result in unexpected pregnancy.

Tydemy is estrogen/progestin oral contraceptive (COC) indicated for use by women to prevent pregnancy and to raise folate levels in women who choose to use an oral contraceptive for contraception. Tydemy is packaged in 28-dose blister packs. One such blister was then packed in a pouch along with one printed sleeve, one pack insert (with day label) and one oxygen absorber (Stabilox) sachet. The three pouches were packed in one carton.

What this means to you:

Patients taking Tydemy are advised to continue taking their medication and immediately contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment.

Wholesalers, distributors and retailers that have Tydemy that is being recalled should discontinue distribution of the recalled product lots immediately.

Consumers, wholesalers, distributors, and retailers with questions regarding this recall should contact Inmar Rx Solutions, Inc. at **866.480.8206**, Monday–Friday, 9 a.m.–5 p.m. Eastern Standard Time (EST). For reimbursement, please have the recalled lots returned to Inmar Rx Solutions, Inc.; the lot number can be found on the side of the carton. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.