August 1, 2019

COM-2019-034

Recall: Jubilant Cadista Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Drospirenone and Ethinyl Estradiol Tablets, USP, Due to Out-of-Specification Dissolution Test Results

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on July 23, 2019, the US Food and Drug Administration (FDA) issued a statement notifying that Jubilant Cadista Pharmaceuticals Inc. is voluntarily recalling one lot of Drospirenone and Ethinyl Estradiol Tablets, USP, 3 mg/ 0.02mg, 28x3 Blister Pack/Carton to the consumer level. The recall was due to out-of-specification (OOS) dissolution results at the 3-month stability time point (as a result the product efficacy may be decreased due to incomplete absorption of the active ingredients). The affected lots by the recall are detailed below:

Affected Drospirenone and Ethinyl Estradiol Tablets, USP, 3 mg/ 0.02mg, 28x3 Blister Pack/Carton. Each blister card contains 28-film coated, biconvex tablets, in the following order: 24 active pink-color round, unscored, film-coated tablets debossed with a "20" on one side, each containing 3 mg Drospirenone and 0.02 mg Ethinyl Estradiol, and four (4) inert white-color round, unscored, film-coated tablets debossed with a "PL".

1. Product Description: Drospirenone and Ethinyl Estradiol tablets are an estrogen/progestin combination oral contraceptive. NDC Number: 59746-763-43 Indications:	
Lot Number	Expiration Date
183222	**11/2020**

The Pharmacy must:

1. Examine their inventory for the affected lot. All inventory of the affected lot should be quarantined to prevent further distribution to patients.
2. Customers who purchased the impacted product directly from Jubilant Cadista Pharmaceuticals Inc. can call Inmar at 1-855-205-9246 (9:00 a.m. – 5:00 p.m. EDT, Monday – Friday) to arrange for their return.

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3. Consumers with additional questions regarding the recall may contact Jubilant Cadista by phone at 1-800-308-3985 (9:00 a.m. – 6:00 p.m. EDT, Monday – Friday).

For additional information visit:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/jubilant-cadista-pharmaceuticals-inc-issues-voluntary-nationwide-recall-drospirenone-and-ethinyl

Clinical Department

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