Apotex – Recall of drospirenone and ethinyl estradiol tablets

- On March 4, 2019, Apotex announced a voluntary, consumer-level recall of four lots of drospirenone and ethinyl estradiol tablets because some may possibly contain defective blisters with incorrect tablet arrangements and/or an empty blister pocket.

- The affected drospirenone and ethinyl estradiol tablets include the following lots and can be identified by NDC numbers stated on the inner and outer cartons:

Product Description	NDC#	Lot# (Expiration Date)
Drospirenone and ethinyl estradiol 3 mg/0.03 mg tablets The outer carton: contains three inner cartons. The inner carton contains 1 blister with 21 active yellow color tablets and 7 placebo white color tablets.	60505-4183-3 (outer carton); 60505-4183-1 (inner carton)	7DY008A (8/2020); 7DY009A (8/2020); 7DY010A (8/2020); 7DY011A (8/2020)

- Drospirenone and ethinyl estradiol tablets are indicated for use by women to prevent pregnancy.

- Per Apotex, as a result of this packaging error, where a patient does not take a tablet due to a missing tablet or that a patient takes a placebo instead of an active tablet, loss of efficacy is possible due to variation in the dosage consumed. To date, no case has been reported for pregnancy and adverse event to Apotex.

    — Drospirenone and ethinyl estradiol tablets (inner carton) consists of 28 film-coated, biconvex tablets in the following order: 21 yellow color tablets, each containing 3 mg drospirenone and 0.03 mg ethinyl estradiol, and 7 placebo white color tablets.

- Patients who have received impacted lots of drospirenone and ethinyl estradiol tablets, or have questions regarding this recall should contact their pharmacy. Patients should use a non-hormonal method of birth control, not interrupt their therapy, and contact their healthcare provider for medical advice. Patients may return the impacted packages to their pharmacy.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled drospirenone and ethinyl estradiol tablets.

- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.

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- For more information regarding this recall, contact Apotex by phone at 1-800-706-5575 or email at **UScustomerservice@Apotex.com**.

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