April 6, 2021 **COM-2021-018**

RECALL NOTIFICATION

FDA PUBLICATION DATE:

March 31, 2021

DRUG NAME: Guanfacine Extended-Release Tablets 2mg

COMPANY: Apotex Corp.

REASON: Trace amounts of Quetiapine Fumarate

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug recalls. It is for this reason that we are notifying you that on March 31, 2021, the U.S. Food and Drug Administration (FDA) published a voluntary drug recall for one lot of the following product: Guanfacine Extended-Release Tablets 2mg, manufactured by Apotex Corp.

Affected product:

NDC	Product description	Lot #	Expiration Date
60505-3928-01	Guanfacine Extended-Release 2mg Tablets	RX1662	11/2022
		RX1663	11/2022
		RX1664	11/2022

The voluntary recall is due to trace amounts of Quetiapine Fumarate found in one Lot Rx1663 of the product. Guanfacine is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Quetiapine is indicated for the treatment of Schizophrenia, Bipolar disorder manic episodes, Bipolar disorder, and depressive episodes. The combination of these two drugs can lead to hypersensitivity reaction, lower blood pressure, sleepiness/sedation, and dizziness. The company has not received any reports of adverse events related to this recall. Patients with the impacted lot should not discontinue use until speaking with their pharmacist and immediately contact their healthcare provider for a replacement.

Pharmacy required action(s):

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.
- Advise patients that they should not discontinue using the medication without contacting their healthcare provider for guidance or a replacement prescription.
- Advise patients to contact their physician if they have experienced any problems related to taking or using this product.

Contact information: For further details, contact Inmar Rx Solutions at 1-855-697-4722 (9:00am – 5:00-pm, EST Monday thru Friday or Apotex Corp. by phone at 1-800-706-5575 (8:30am –5:00pm, EST Monday thru Friday) or email address UScustomerservice@Apotex.com .

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2021). Apotex Corp. Issues Voluntary Nationwide Recall of Guanfacine Extended-Release Tablets 2mg Due to Trace Amounts of Quetiapine Fumarate. Retrieved April 5, 2021 from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-guanfacine-extended-release-tablets-2mg-due-trace