RXADVANCE
136 Turnpike Road
Southborough, MA 01772

Guanfacine Extended-Release Tablets Safety Alert

Date of Notice: 03/31/2021

Brief Description of Safety Alert

Apotex Corp is voluntarily recalling three (3) lots of guanfacine extended-release (ER) tablets 2mg due to trace amounts of quetiapine fumarate in one lot (RX1663). Out of an abundance of caution, lots RX1662 and RX1664 are also included in this voluntary recall, as these lots were manufactured at the same time as lot RX1663.

Risk Statement: Administration of guanfacine extended-release tablets containing trace amounts of quetiapine fumarate to a patient can result in the possibility of hypersensitivity reaction and may potentially have additive effects in lowering blood pressure, sleepiness/sedation, and dizziness. Pediatric patients, pregnant patients, and older adults may be more likely to experience low blood pressure and dizziness if exposed to the defective product.

Guanfacine is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and can be used with other stimulant medications. Quetiapine is indicated for the treatment of schizophrenia and other serious mental disorders such as bipolar disorder manic episodes, bipolar disorder, and depressive episodes.

The affected guanfacine extended-release tablets can be identified by NDC numbers stated on label of the product. The lot number and expiration date are located to the left side of the product description on the label besides the barcode. The affected lots were distributed in the USA between December 22, 2020 to March 19, 2021.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
guanfacine ER 2 mg tablets	60505-3928-01	RX1662	07/2020
guanfacine ER 2 mg tablets	60505-3928-01	RX1663	
guanfacine ER 2 mg tablets	60505-3928-01	RX1664	

Prescriber Information

Wholesalers, distributors, warehousing chains, independent retail pharmacy and retail buying groups should return the recalled product to the place of purchase. Anyone with an existing inventory of the recalled product should quarantine the recalled lots immediately. Customers who purchased the impacted product directly from Apotex can call Inmar Rx Solutions at 1-855-697-4722 (9:00am – 5:00pm, EST Monday thru Friday), to arrange for their return.

To date, Apotex Corp has not received any reports of adverse events related to this recall. 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.
- Regular Mail or Fax: 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.

Member Information

Members who have received any of the three (3) impacted lots of guanfacine ER tablets or have questions regarding this recall should contact their pharmacy. Members should not interrupt their therapy due to this notice. Members should immediately contact their doctor or healthcare provider for medical advice and return the impacted product to Inmar Rx Solutions by contacting at the numbers provided in this press release.

Members with the affected units of guanfacine ER tablets, can contact Inmar Rx Solutions (“Inmar”) at 1-855-697-4722, to receive a recall/return packet including the Recall Stock Response Form, or you may obtain this form clsnetlink.com.

Members with questions regarding this recall can contact Apotex Corp. by phone at 1-800-706-5575 (8:30am –5:00pm, EST Monday thru Friday) or email address UScustomerservice@Apotex.com. Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

RxAdvance Response

RxAdvance recommends that you speak to your doctor or healthcare provider about concerns regarding this safety alert.