Apotex – Recall of guanfacine

- On March 31, 2021 Apotex announced a voluntary, consumer-level recall of three lots of guanfacine 2 mg extended-release tablets because of trace amounts of quetiapine fumarate in one lot.
- The trace quetiapine was found in lot RX1663. Out of an abundance of caution, lots RX1662 and RX1664 are also included in the scope of this voluntary recall, as they were manufactured in the same campaign as lot RX1663.
- The affected lots were distributed between December 22, 2020 to March 19, 2021.

Product Description	NDC#	Lot# (Expiration Date)
Guanfacine 2 mg extended-release tablets, 100-count bottle	60505-3928-1	RX1662 (11/2022); RX1663 (11/2022); RX1664 (11/2022)

- Guanfacine is indicated for the treatment of attention deficit hyperactivity disorder 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.
- 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.
- To date, Apotex has not received any reports of adverse events related to this recall.
- 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 2D barcode.
- Consumers that may have the recalled guanfacine 2 mg extended-release tablets should not discontinue use until speaking with their pharmacist or healthcare professional for a replacement. Recalled product should be returned to Inmar Rx Solutions at **1-855-697-4722**.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled guanfacine.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.

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- Contact Apotex by phone at **1-800-706-5575** or by email at **UScustomerservice@Apotex.com** for more information about this recall.

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