APOTEX
Canadian-Based
Global Health Company

Public Communication
Important Safety Information on APO-QUETIAPINE XR (quetiapine fumarate extended-release tablets)

January 30, 2025

Subject: Voluntary Recall of five (5) lots of APO-QUETIAPINE XR (quetiapine fumarate extended-release tablets)

Apotex Inc. ("Apotex"), in coordination with the Regulatory Operations and Enforcement Branch (ROEB) of Health Canada, is initiating a voluntary **TYPE I** recall to the **Pharmacy Level** for five (5) lots of "**APO-QUETIAPINE XR (quetiapine fumarate extended-release tablets)**".

APO-QUETIAPINE XR (quetiapine fumarate extended-release tablets) lots are manufactured by Intas Pharmaceutical Limited.

This recall is being initiated due to one (1) lot in which the acceptable intake limit of 400 ng/day for N-nitroso-desalkyl-quetiapine (also known as N-nitroso-aryl piperazine), as established by Health Canada, has been exceeded. Out of an abundance of caution, the company extends the recall to include four (4) additional lots as all five (5) lots have consumed the same drug substance lot. There have been no reports of relevant adverse event or complaints received for any of these five (5) lots between January 3, 2023 and January 27, 2025. The details for the lots being recalled are listed below:

PRODUCT	DIN	UPC on Bottle	STRENGTH	SIZE / FORMAT	LOT	EXP. DATE (mm/yyyy)	First Date of Sale (mm/dd/yyyy)	Last Date of Sale (mm/dd/yyyy)
APO-QUETIAPINE XR (quetiapine fumarate extended-release tablets)	02457229	771313244121	50 mg	60 BTL	M2213002	08/2025	04/15/2023	06/19/2023
	02457229	771313244121	50 mg	60 BTL	M2213003	08/2025	05/12/2023	06/27/2023
	02457229	771313244121	50 mg	60 BTL	M2214445	08/2025	01/03/2023	11/14/2023
	02457245	771313244145	200 mg	60 BTL	M2214011	10/2025	02/04/2023	07/06/2023
	02457245	771313244145	200 mg	60 BTL	M2214015	10/2025	04/25/2023	08/29/2023

According to the Canadian Product Monograph dated November 01, 2022, APO-Quetiapine Fumarate extended release (XR) 50 mg, 150 mg, 200 mg, 300 mg and 400 mg oral tablets is indicated for the following conditions:

Schizophrenia
APO-QUETIAPINE XR (quetiapine fumarate extended release) is indicated for:

- the management of the manifestations of schizophrenia.

Bipolar disorder
APO-QUETIAPINE XR is indicated as monotherapy for the:

- acute management of manic episodes associated with bipolar disorder.
- acute management of depressive episodes associated with bipolar I and bipolar II disorder.

Major Depressive Disorder
APO-QUETIAPINE XR is indicated for:

- the symptomatic relief of major depressive disorder (MDD) when currently available approved antidepressant drugs have failed either due to lack of efficacy and/or lack of tolerability.

The safety and efficacy of APO-QUETIAPINE XR in pediatric patients has not been established.

APO-QUETIAPINE XR is not indicated in elderly patients with dementia.

To report a suspected adverse reaction associated with the use of **APO-QUETIAPINE XR (quetiapine fumarate extended-release tablets)** patients may contact Apotex by calling **1-800-667-4708 or 416-401-7780** (follow prompts), by email at drug.safety@apotex.com or by fax at **1-866-429-9133 or 416-401-3819**.

Patients may also report any suspected adverse reactions associated with the use of health products to Health Canada by calling toll free at **1-866-234-2345** or by visiting MedEffect Canada's Web page on Adverse Reaction Reporting https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html for information on how to report online, by mail or by fax.