



APO-AMITRIPTYLINE 10mg (2021-04-13)

Report a Concern
(<http://www.healthycanadians.gc.ca/report-signalez/index-eng.php>)

Starting date: April 13, 2021
Type of communication: Drug Recall
Subcategory: Drugs
Hazard classification: Type I
Source of recall: Health Canada
Issue: Product Safety
Audience: General Public, Healthcare Professionals, Hospitals
Identification number: RA-75397

Last updated: 2021-04-14

Summary

- **Product:** APO-AMITRIPTYLINE 10mg

- [Reason](#)
- [Depth of distribution](#)
- [Affected products](#)

Reason

Presence of higher than accepted levels of a nitrosamine impurity known as N-nitrosodimethylamine (NDMA) in the affected lot.

Depth of distribution

Retailers, Wholesalers, Healthcare Establishments

Affected products

APO-AMITRIPTYLINE

DIN, NPN, DIN-HIM

DIN 02403137

Dosage form

Tablet

Strength

AMITRIPTYLINE HYDROCHLORIDE 10mg

Lot or serial number

RF0410

Companies

Recalling Firm Apotex Inc.
150 Signet Drive
Toronto
M9L 1T9
Ontario
CANADA

Marketing Authorization Holder Apotex Inc.
150 Signet Drive
Toronto
M9L 1T9
Ontario
CANADA

