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TEVA-LOSARTAN/HCTZ (2019-03-06)

Report a Concern (http://www.healthycan adians.gc.ca/reportsignalez/indexeng.php)

March 6, 2019 Starting date: Type of communication: Drug Recall Subcategory: Drugs Hazard classification: Type I

Health Canada Source of recall: Issue: **Product Safety**

Audience: General Public, Healthcare Professionals, Hospitals

Identification number: RA-69266

Reason Depth of distribution Affected products

Recalled Products

Teva-Losartan / HCTZ 50/12.5mg Tablet

Reason

Affected lots manufactured with an API that may contain the impurity N-nitroso-N-methyl-4-aminobutyric acid (referred as "NMBA") above the acceptable level.

Depth of distribution

Retailers

Affected products

Teva-Losartan / HCTZ 50/12.5mg Tablet

DIN, NPN, DIN-HIM

DIN 02358263

Dosage form

Tablet

Strength

Hydrochlorothiazide 12.5mg Losartan potassium 50.0mg

Lot or serial number

35344801A, 35349397A

Companies

Recalling Firm Teva Canada Ltd.

30 Novopharm Court

Toronto M1B 2K9 Ontario **CANADA**

Teva Canada Ltd. Marketing Authorization Holder

30 Novopharm Court

Toronto M1B 2K9 Ontario CANADA

Date modified: 2019-03-11