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Teva Canada Product Recall (2018-11-23)

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

Starting date: November 23, 2018

Type of communication: Drug Recall Subcategory: Drugs Hazard classification: Type III Health Canada Source of recall: Issue: **Product Safety**

Audience: General Public, Healthcare Professionals, Hospitals

Identification number: RA-68408

Reason Depth of distribution Affected products

Recalled Product

A. Novamoxin Granules for Oral Suspension 125mg/5mL

B. Novamoxin Granules for Oral Suspension 250mg/5mL

Reason

Out of specification results for homogeneity.

Depth of distribution

Retailers

Affected products

A. Novamoxin Granules for Oral Suspension 125mg/5mL

DIN, NPN, DIN-HIM

DIN 00452149

Dosage form

Granules for suspension

Strength

Amoxicillin 125mg/5mL

Lot or serial number

35438292B. 35438811A

Companies

Recalling Firm Teva Canada Ltd.

30 Novopharm Court

Toronto M1B 2K9 Ontario CANADA

Marketing Authorization Holder Teva Canada Ltd.

30 Novopharm Court

Toronto M1B 2K9 Ontario CANADA

B. Novamoxin Granules for Oral Suspension 250mg/5mL

DIN, NPN, DIN-HIM

DIN 00452130

Dosage form

Granules for suspension

Strength

Amoxicillin 250mg/5mL

Lot or serial number

35439807A

Companies

Recalling Firm Teva Canada Ltd.

30 Novopharm Court

Toronto M1B 2K9 Ontario CANADA

Marketing Authorization Holder Teva Canada Ltd.

30 Novopharm Court

Toronto M1B 2K9 Ontario CANADA

Date modified: 2018-11-27