Sivem Pharmaceuticals ULC Ranitidine Product Recall (2019-10-17)

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

Starting date:	October 17, 2019
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-71357

Last updated: 2019-10-21

Summary

- **Product:** A. Ranitidine 300 mg Tablet; B. Ranitidine 150 mg Tablet

A. Ranitidine 300 mg Tablet;

B. Ranitidine 150 mg Tablet

Reason

Affected lots may be manufactured with an API containing an impurity, N-nitrosodimethylamine (NDMA).

Depth of distribution

Wholesalers, Healthcare Establishments, Retailers

Affected products

A. Ranitidine 300 mg Tablet

DIN, NPN, DIN-HIM

DIN 02385961

Dosage form

Tablet

Strength

Ranitidine 300 mg

Lot or serial number

K50941, K50624, K50947, K50950

Companies

Recalling Firm

Sivem Pharmaceuticals ULC
4705 Dobrin Street
Saint-Laurent
H4R 2P7
Quebec
CANADA

Marketing Authorization Holder Sivem Pharmaceuticals ULC
4705 Dobrin Street
Saint-Laurent
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CANADA

B. Ranitidine 150 mg Tablet

DIN, NPN, DIN-HIM

DIN 02385953

Dosage form

Tablet

Strength

Ranitidine 150 mg

Lot or serial number

K46484, K50204, K46485, K50206, K50590, K50677, K50908, K48440, K48679, K50207, K50594, K50925, K50928, K50932, K50935, K51080

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For more information

https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/71029a-eng.php (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/71029a-eng.php)

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