Sivem Pharmaceuticals ULC Ranitidine Product Recall (2019-09-24)

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

Starting date:	September 24, 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-71065

Last updated: 2019-09-25

A. Sivem Ranitidine 150 mg

B. Sivem Ranitidine 300 mg

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. Sivem Ranitidine 150 mg

DIN, NPN, DIN-HIM

DIN 02385953

Dosage form

Tablet

Strength

Ranitidine hydrochloride 150 mg

Lot or serial number

NP4183, NT2757, NT2764, NT2765, PJ2435, NP4184, NT2724, NT2762, NT2763, NP4179, NP5656, NP5657, NT2721, NT2722, PJ2434, PV6243, PV6244, PV6245

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
H4R 2P7
Quebec
CANADA

B. Sivem Ranitidine 300 mg

DIN, NPN, DIN-HIM

DIN 02385961

Dosage form

Tablet

Strength

Ranitidine hydrochloride 300 mg

Lot or serial number

NP4177, NP4180, NT1365, PX8854

Companies

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4705 Dobrin Street
Saint-Laurent
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Quebec
CANADA

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For more information

http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70989a-eng.php (http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70989a-eng.php)

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