

Sivem-Losartan Product Recall (2021-05-26)

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

Starting date: May 26, 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-75693

Last updated: 2021-05-31

Summary

Product:

1. Sivem-Losartan 25 mg Tablet
2. Sivem-Losartan 50 mg Tablet
3. Sivem-Losartan 100 mg Tablet

Reason

Depth of distribution

Affected products

1. Sivem-Losartan 25 mg Tablet
2. Sivem-Losartan 50 mg Tablet
3. Sivem-Losartan 100 mg Tablet

Reason

Presence of impurity 5-(4-(azidomethyl)-[1,1-biphenyl]-2-yl)-1H-tetrazole above the acceptable concentration limit in affected lots.

Depth of distribution

Retailers

Affected products

1. Sivem-Losartan 25 mg Tablet

DIN, NPN, DIN-HIM

DIN 02388790

Dosage form

Tablet

Strength

Losartan Potassium 25mg

Lot or serial number

0050919, 0060919, 0070919, 0080919, 0080919A, 0101019, 0101019A, 0030120, 0040120, 0080620, 0090620

Companies

Recalling Firm

Sivem Pharmaceuticals ULC
4705 Dobrin Street
St. Laurent
H4R 2P7
Quebec
CANADA

Marketing Authorization Holder Sivem Pharmaceuticals ULC
4705 Dobrin Street
St. Laurent
H4R 2P7
Quebec
CANADA

B. Sivem-Losartan 50 mg Tablet

DIN, NPN, DIN-HIM

DIN 02388804

Dosage form

Tablet

Strength

Losartan Potassium 50mg

Lot or serial number

1121018, 1131018, 1130819, 1140819, 1150819, 1160819, 1170919, 1180919, 1070220, 1080220, 1090220, 1100220, 1110220, 1060220, 1120620

Companies

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4705 Dobrin Street
St. Laurent
H4R 2P7
Quebec
CANADA

Marketing Authorization Holder Sivem Pharmaceuticals ULC
4705 Dobrin Street
St. Laurent
H4R 2P7
Quebec
CANADA

C. Sivem-Losartan 100 mg Tablet

DIN, NPN, DIN-HIM

DIN 02388812

Dosage form

Tablet

Strength

Losartan Potassium 100mg

Lot or serial number

2070817, 2040218, 2101018, 2020219, 2030219, 2040219, 2090619, 2100919, 2110919, 2120919, 2130919, 2140919, 2151119, 2050420, 2060420

Companies

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St. Laurent
H4R 2P7
Quebec
CANADA

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4705 Dobrin Street
St. Laurent
H4R 2P7
Quebec
CANADA

For more information

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75715a-eng.php> (<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75715a-eng.php>).

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