

Sandoz Canada Losartan/Losartan-HCT Product Recall (2021-09-13)

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

Starting date:	September 13, 2021
Posting date:	September 16, 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-76435

Last updated: 2021-09-16

Summary

Product:

1. Losartan 25 mg Tablet
2. Losartan 50 mg Tablet
3. Losartan 100 mg Tablet
4. Losartan/HCT 50 mg / 12.5 mg Tablet
5. Losartan/HCT 100 mg / 12.5 mg Tablet
6. Losartan/HCT 100 mg / 25 mg Tablet

Reason Depth of distribution Affected products

1. Losartan 25 mg Tablet
2. Losartan 50 mg Tablet
3. Losartan 100 mg Tablet
4. Losartan/HCT 50 mg / 12.5 mg Tablet
5. Losartan/HCT 100 mg / 12.5 mg Tablet
6. Losartan/HCT 100 mg / 25 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

Losartan 25 mg Tablet

DIN, NPN, DIN-HIM

DIN 02313332

Dosage form

Tablet

Strength

Losartan Potassium 25 mg

Lot or serial number

KF3703, KF3704, KR0055, KS3238, KV8085, KY3612

Companies

Recalling Firm Sandoz Canada Incorporated
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Marketing Authorization Holder Sandoz Canada Incorporated
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Losartan 50 mg Tablet

DIN, NPN, DIN-HIM

DIN 02313340

Dosage form

Tablet

Strength

Losartan Potassium 50 mg

Lot or serial number

KF3629, KS1008, KS1009, KS8837, KT8356, KY8356, KY7473, KS1006, KY7472

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Losartan 100 mg Tablet

DIN, NPN, DIN-HIM

DIN 02313359

Dosage form

Tablet

Strength

Losartan Potassium 25 mg

Lot or serial number

KF3630, KR6172, KS7551, LA1962, LD1621, LJ2275, KR6171, LA0665

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Losartan/HCT 50 mg / 12.5 mg Tablet

DIN, NPN, DIN-HIM

DIN 02313375

Dosage form

Tablet

Strength

Hydrochlorothiazide 12.5 mg, Losartan Potassium 50 mg

Lot or serial number

KF3705, KF3706, KR8908, KS7564, KX6497, LB3649, KR7041, KS5626, KS5627, KX6500

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Losartan/HCT 100 mg / 12.5 mg Tablet

DIN, NPN, DIN-HIM

DIN 02362449

Dosage form

Tablet

Strength

Hydrochlorothiazide 12.5 mg, Losartan Potassium 100 mg

Lot or serial number

KF3628, KS3893, KT2043, KY9842, LB1657, KF3714, KS3889, KS3890, KT2044, KY9846

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Losartan/HCT 100 mg / 25 mg Tablet

9/28/21, 5:56 PM

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DIN, NPN, DIN-HIM

DIN 02313383

Dosage form

Tablet

Strength

Hydrochlorothiazide 25 mg, Losartan Potassium 100 mg

Lot or serial number

KG4858, KU3078, KS3076, KZ7522, KG4859, KS3077, KZ7520

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For more information

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

Date modified: 2021-09-16