

# Sandoz-Irbesartan/HCT Product Recall (2021-05-27)

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

**Starting date:** May 27, 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-75699

Last updated: 2021-05-31

## Summary

### Product:

1. Sandoz Irbesartan/HCT 150/12.5 mg Tablet
2. Sandoz Irbesartan/HCT 300/12.5 mg Tablet
3. Sandoz Irbesartan/HCT 300/25 mg Tablet

### Reason

### Depth of distribution

### Affected products

1. Sandoz Irbesartan/HCT 150/12.5 mg Tablet
2. Sandoz Irbesartan/HCT 300/12.5 mg Tablet
3. Sandoz Irbesartan/HCT 300/25 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

### A. Sandoz Irbesartan/HCT 150/12.5 mg Tablet

DIN, NPN, DIN-HIM

DIN 02337428

Dosage form

Tablet

Strength

Irbesartan 150 mg

Hydrochlorothiazide 12.5 mg

Lot or serial number

JF5840, JN4197, JN4971, JU3217, JV2167, JF8892, JN4191

Companies

#### Recalling Firm

Sandoz Canada Inc  
 110 de Lauzon  
 Boucherville  
 J4B 1E6

Quebec  
CANADA

**Marketing Authorization Holder** Sandoz Canada Inc  
110 de Lauzon  
Boucherville  
J4B 1E6  
Quebec  
CANADA

### B. Sandoz Irbesartan/HCT 300/12.5 mg Tablet

DIN, NPN, DIN-HIM

DIN 02337436

Dosage form

Tablet

Strength

Irbesartan 300 mg

Hydrochlorothiazide 12.5 mg

Lot or serial number

JK7459, JK7460, JM3516, JM3517, JR7821, JU7500, JU7501, JU7502, JU7503, JY0147, JE2529, JM4631, JZ2686

Companies

**Recalling Firm** Sandoz Canada Inc  
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Boucherville  
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Quebec  
CANADA

**Marketing Authorization Holder** Sandoz Canada Inc  
110 de Lauzon  
Boucherville  
J4B 1E6  
Quebec  
CANADA

### C. Sandoz Irbesartan/HCT 300/25 mg Tablet

DIN, NPN, DIN-HIM

DIN 02337444

Dosage form

Tablet

Strength

Irbesartan 300 mg

Hydrochlorothiazide 25 mg

Lot or serial number

JB0221, JB0222, JC4402, JC4404, JH2487, JR7112, JR7833, JU3181, JW9512, JW9513, KC1750, JE1833, JR8726

Companies

**Recalling Firm** Sandoz Canada Inc  
110 de Lauzon  
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**Marketing Authorization Holder** Sandoz Canada Inc  
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**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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