

MINT-Irbesartan/HCTZ 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-75697

Last updated: 2021-05-31

Summary

Product:

1. MINT-Irbesartan/HCTZ 150/12.5 mg Tablet
2. MINT-Irbesartan/HCTZ 300/12.5 mg Tablet
3. MINT-Irbesartan/HCTZ 300/25 mg Tablet

Reason

Depth of distribution

Affected products

1. MINT-Irbesartan/HCTZ 150/12.5 mg Tablet
2. MINT-Irbesartan/HCTZ 300/12.5 mg Tablet
3. MINT-Irbesartan/HCTZ 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, Wholesalers

Affected products

A. MINT-Irbesartan/HCTZ 150/12.5 mg Tablet

DIN, NPN, DIN-HIM

DIN 02392992

Dosage form

Tablet

Strength

Irbesartan 150 mg

Hydrochlorothiazide 12.5 mg

Lot or serial number

1805011398

Companies

Recalling Firm

Mint Pharmaceuticals Inc
6575 Davand Drive
Mississauga
L5T 2M3

Ontario
CANADA

Marketing Authorization Holder Mint Pharmaceuticals Inc
6575 Davand Drive
Mississauga
L5T 2M3
Ontario
CANADA

B. MINT-Irbesartan/HCTZ 300/12.5 mg Tablet

DIN, NPN, DIN-HIM

DIN 02393018

Dosage form

Tablet

Strength

Irbesartan 300 mg

Hydrochlorothiazide 12.5 mg

Lot or serial number

1805011402

Companies

Recalling Firm Mint Pharmaceuticals Inc
6575 Davand Drive
Mississauga
L5T 2M3
Ontario
CANADA

Marketing Authorization Holder Mint Pharmaceuticals Inc
6575 Davand Drive
Mississauga
L5T 2M3
Ontario
CANADA

C. MINT-Irbesartan/HCTZ 300/25 mg Tablet

DIN, NPN, DIN-HIM

DIN 02393026

Dosage form

Tablet

Strength

Irbesartan 300 mg

Hydrochlorothiazide 25 mg

Lot or serial number

1805011576

Companies

Recalling Firm Mint Pharmaceuticals Inc
6575 Davand Drive
Mississauga
L5T 2M3
Ontario
CANADA

Marketing Authorization Holder Mint Pharmaceuticals Inc
6575 Davand Drive
Mississauga
L5T 2M3

Ontario
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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