Lupin – Recall of irbesartan and irbesartan/hydrochlorothiazide (HCTZ)

- On October 12, 2021, Lupin announced a consumer level recall of irbesartan and irbesartan/HCTZ tablets because certain active pharmaceutical ingredient (API) batches were above the specification limit for N-nitrosoirbesartan impurity.
    - Clinical Services through the Drug Safety Notification program will conduct a mailing to members and send electronic messaging to providers that may be affected by this recall.
    - The letters instruct members to contact Inmar Rx (appointed company for Lupin) for refund and return information.
    - Other irbesartan and irbesartan/HCTZ tablets that are not being recalled are available for patients to use.

- The recalled irbesartan and irbesartan/HCTZ lots were shipped from October 2018 to December 2020.

Product Description	NDC#	Lot# (Expiration Date)
Irbesartan 75 mg tablets	68180-410-06	H901579 (03/31/2022); H000843 (02/28/2023); H805727 (11/30/2021)
	68180-410-09	H000964 (03/31/2023); H901578 (03/31/2022); H901577 (03/31/2022); H901497 (01/31/2022); H805726 (11/30/2021); H805725 (11/30/2021); H805269 (11/30/2021); H805268 (11/30/2021); H804311 (08/31/2021); H902258 (05/31/2022); H000844 (02/28/2023); H805267 (11/30/2021)
Irbesartan 150 mg tablets	68180-411-06	H804403 (08/31/2021); H805251 (11/30/2021); H805640 (11/30/2021); H901580 (04/30/2022)
	68180-411-09	H902140 (04/30/2022); H805252 (11/30/2021); H805253 (11/30/2021); H805641 (11/30/2021); H805642 (11/30/2021); H805643 (11/30/2021); H901581 (04/30/2022); H902139 (04/30/2022); H804492 (08/31/2021)

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Irbesartan 300 mg tablets	68180-412-06	H804310 (08/31/2021); H900050 (11/30/2021); H902262 (05/31/2022)
	68180-412-09	H805724 (11/30/2021); H000845 (02/28/2023); H000846 (02/28/2023); H000965 (03/31/2023); H805345 (11/30/2021); H805346 (11/30/2021); H900061 (12/31/2021); H900062 (12/31/2021); H900445 (01/31/2022); H901489 (03/31/2022); H901490 (03/31/2022); H901491 (03/31/2022); H902261 (05/31/2022); H805347 (11/30/2021)
Irbesartan/HCTZ 150 mg/12.5 mg tablets	68180-413-06	H804537 (09/30/2021); H805148 (10/31/2021); H900063 (12/31/2021); H900522 (01/31/2022); H901582 (04/30/2022)
	68180-413-09	H000963 (03/31/2023) H804536 (09/30/2021); H805070 (10/31/2021); H805149 (10/31/2021); H900523 (01/31/2022); H900064 (03/31/2023); H901583 (04/30/2022); H804507 (09/30/2021); H902530 (04/30/2022)
Irbesartan/HCTZ 300 mg/12.5 mg tablets	68180-414-06	H804192 (08/31/2021); H805348 (11/30/2021); H900065 (12/31/2021); H902264 (05/31/2022)
	68180-414-09	H805349 (11/30/2021); H805350 (11/30/2021); H900066 (12/31/2021); H900067 (12/31/2021); H804082 (08/31/2021); H902265 (05/31/2022); H804121 (08/31/2021); H902275 (05/31/2022); H804338 (08/31/2021); H902276 (05/31/2022); H804538 (09/30/2021); H902531 (04/30/2022); H804539 (09/30/2021); H902532 (04/30/2022)

- N-nitrosoirbesartan impurity is a probable human carcinogen based on results from laboratory tests.
- Irbesartan and irbesartan/HCTZ tablets are indicated for the treatment of hypertension (HTN). Irbesartan is also indicated for the treatment of diabetic nephropathy in patients with type 2 diabetes and HTN, an elevated serum creatinine, and proteinuria (> 300 mg/day).

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled irbesartan products.

- Patients with the recalled irbesartan or irbesartan/HCTZ on hand should contact Inmar Rx at **1-855-769-3988** for return and refund information.

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