

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Lupin Pharmaceuticals Inc. is initiating a recall of 15 lots of **Irbesartan Tablets USP, 75mg**, 13 lots of **Irbesartan Tablets USP, 150mg** and 17 lots of **Irbesartan Tablets USP, 300mg** to the **consumer** level. As part of Lupin's ongoing assessment, analysis revealed that certain tested API batches were above the specification limit for N-nitrosoirbesartan impurity.

**Irbesartan Tablets USP, 75mg:**

Lot No	Expiry Date	NDC	Lot No	Expiry Date	NDC
H000843	28/02/2023	68180-410-06	H805269	30/11/2021	68180-410-09
H805727	30/11/2021	68180-410-06	H805725	30/11/2021	68180-410-09
H901579	31/03/2022	68180-410-06	H805726	30/11/2021	68180-410-09
H000844	28/02/2023	68180-410-09	H901497	31/01/2022	68180-410-09
H000964	31/03/2023	68180-410-09	H901577	31/03/2022	68180-410-09
H804311	31/08/2021	68180-410-09	H901578	31/03/2022	68180-410-09
H805267	30/11/2021	68180-410-09	H902258	31/05/2022	68180-410-09
H805268	30/11/2021	68180-410-09			

**Irbesartan Tablets USP, 150mg:**

Lot No	Expiry Date	NDC	Lot No	Expiry Date	NDC
H804403	31/08/2021	68180-411-06	H805641	30/11/2021	68180-411-09
H805251	30/11/2021	68180-411-06	H805642	30/11/2021	68180-411-09
H805640	30/11/2021	68180-411-06	H805643	30/11/2021	68180-411-09
H901580	30/04/2022	68180-411-06	H901581	30/04/2022	68180-411-09
H804492	31/08/2021	68180-411-09	H902139	30/04/2022	68180-411-09
H805252	30/11/2021	68180-411-09	H902140	30/04/2022	68180-411-09
H805253	30/11/2021	68180-411-09			

**Irbesartan Tablets USP, 300mg:**

Lot No	Expiry Date	NDC	Lot No	Expiry Date	NDC
H804310	31/08/2021	68180-412-06	H805724	30/11/2021	68180-412-09
H900050	30/11/2021	68180-412-06	H900061	31/12/2021	68180-412-09
H902262	31/05/2022	68180-412-06	H900062	31/12/2021	68180-412-09

Lot No	Expiry Date	NDC	Lot No	Expiry Date	NDC
H000845	28/02/2023	68180-412-09	H900445	31/01/2022	68180-412-09
H000846	28/02/2023	68180-412-09	H901489	31/03/2022	68180-412-09
H000965	31/03/2023	68180-412-09	H901490	31/03/2022	68180-412-09
H805345	30/11/2021	68180-412-09	H901491	31/03/2022	68180-412-09
H805346	30/11/2021	68180-412-09	H902261	31/05/2022	68180-412-09
H805347	30/11/2021	68180-412-09			

The recalled lots were distributed between October 20, 2018 and December 3, 2020 to wholesalers, drug chains, mail order pharmacies nationwide. Irbesartan Tablets USP are supplied as:

Strength	NDC's	Pack	Description
75mg	68180-410-06	30's,	White to off-white, oval shaped, uncoated tablets, debossed with a LU on one side and M11 on the other side.
	68180-410-09	90's	
150mg	68180-411-06	30's,	White to off-white, oval shaped, uncoated tablets, debossed with a LU on one side and M12 on the other side.
	68180-411-09	90's	
300mg	68180-412-06	30's,	White to off-white, oval shaped, uncoated tablets, debossed with a LU on one side and M13 on the other side.
	68180-412-09	90's	