



Ireland

Teva Pharmaceuticals Ireland

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## BATCH RECALL

Product Name	Marketing Authorisation No.	Batch No.	Expiry Date
Irprezide 150mg/12.5mg Film-Coated Tablets (Irbesartan/Hydrochlorothiazide)	PA 1380/80/1	150118	04/2020
Irprezide 300mg/12.5mg Film-Coated Tablets (Irbesartan/Hydrochlorothiazide)	PA 1380/80/2	059118	03/2020

21st December 2018

Dear Wholesaler,

We wish to advise you that the batch no. 150118 of Irprezide 150mg/12.5mg Film-Coated Tablets and batch no. 059118 of Irprezide 300mg/12.5mg Film-Coated Tablets are being recalled with immediate effect.

This recall is going to **pharmacy level**.

This action has been agreed with the Health Products Regulatory Authority.

The reason for the recall is due to the detection of an impurity, N-nitrosodiethylamine (NDEA) in the irbesartan active substance lots used in the manufacture of the above batches of products. The active substance lots were manufactured at Zhejiang Huahai Pharmaceutical Co. Ltd., China.

Please immediately quarantine any units of the above referenced batches which you have in your possession. Please also facilitate any returns from retail/hospital pharmacies.

Please return all quarantined units to United Drug Distributors Ireland Limited, United Drug House, Magna Drive, Magna Business Park, Citywest, Dublin 24 by 25th January 2019 for credit.

If you have supplied either of these batches of products to any other wholesalers, please contact and provide them with a copy of this recall letter, requesting that they quarantine and return any unsold stock from these batches to you.

We are endeavouring to make replacement stock of these products available as soon as possible. It is not known at this time when replacement stock will be available. Please note that stock of Irprezide 300mg/25mg Film-Coated Tablets is not impacted by this recall action.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Kevin Woods at telephone number 042 936498 / 087 2392797 or email at kevin.woods@teva.ie

Yours sincerely,

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