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 Pharmacist,

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.** Please note that there is no requirement to contact patients.

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. This impurity (NDEA) has been classified as a probable human carcinogen.

At present there is no evidence that this impurity has caused any harm to patients, however this recall action is being undertaken as a precautionary measure to prevent any further exposure to the impurity in the affected medicines whilst the investigation is ongoing.

Please perform the following actions:

1. Please immediately quarantine any units of the batches of products detailed above which remain within your pharmacy. For hospital pharmacies, this includes wards, clinics and any other relevant locations within the hospital.

2. Quarantined stock should be returned via the wholesaler from whom you sourced the product. Please return quarantined units to your wholesaler for full credit by 11th January 2019.

3. Hospital Pharmacists: Please inform relevant prescribers within your hospital of this recall action so that they are made aware of it.

IMPORTANT: There is no requirement to contact patients, as this is a pharmacy level recall.

If you have supplied units from either of these batches of products to another pharmacy or clinic, please forward a copy of this letter to them so that they can perform the requested actions.

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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