

Batch Recall

Product name	PA number	Batch number	Expiry date
Irprestan 150 mg film-coated tablets	PA 1380/21/2	136918	03/2020

04 February 2019

Dear Pharmacist,

We wish to advise you that batch number 136918 of Irprestan (Irbesartan) 150 mg film-coated tablets, PA 1380/21/2, is 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 (HPRA).

The reason for the recall is due to the detection of an impurity, N-nitrosodiethylamine (NDEA), in one of the two Irbesartan active substance lots used in the manufacture of this finished product batch. Based on the levels of NDEA found in the active substance lot, it was subsequently confirmed that the NDEA level in the finished product batch was above the acceptable limit.

The active substance lot was manufactured at Zhejiang Huahai Pharmaceutical Co. Ltd. in 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 medicine whilst the investigation is ongoing.

Please perform the following actions:

1. Please immediately quarantine any units from the above-listed batch which you have in your pharmacy. For hospital pharmacies, this includes wards, clinics and any other relevant locations within your hospital.
2. Please return the quarantined stock to the wholesaler from which you sourced the batch. Credit will be issued for stock returned within 14 days of receipt of this letter.
3. Hospital pharmacists are requested to inform relevant prescribers within their hospital of this recall action so that they are made aware of it.

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

If you have supplied units from this batch 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 this product available as soon as possible. It is expected that replacement stock may be available in April.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact our Medical Information team at telephone number +0044 (0) 1271 385257.

Yours sincerely,



Natasha O'Sullivan
QA Leader & Responsible Person



The Evolution of Generics

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