

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 Wholesaler,

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 action going to **pharmacy level**.

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 the 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.

Please immediately quarantine any units from this batch which you have in your possession. Please also facilitate any returns from retail/hospital pharmacies.

Please return all quarantined units to Allphar Services Limited, Unit 645 & 646 Jordanstown Drive, Greenogue Business Park, Rathcoole, Co. Dublin within 4 weeks of receipt of this letter for credit.

If you have supplied this batch to any other wholesaler(s), please contact those wholesaler(s) and provide them with a copy of this recall letter, requesting that they quarantine and return any unsold stock from this batch to you.

We are endeavouring to make replacement stock of this product available as soon as possible. It is expected that replacement stock may be available again in April.

Directors: Nadine Jakes (UK), Jonathan Wilson (UK), Tony Hynds

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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 or alternatively please contact my direct line, 021 240 8270, for any further queries.

Yours sincerely,

A handwritten signature in blue ink that reads "Natasha O'Sullivan". The signature is written in a cursive style and is positioned above a horizontal line.

Natasha O'Sullivan
QA Leader & Responsible Person

The logo for Accord Healthcare, featuring the word "accord" in a lowercase, sans-serif font. The letters "a", "c", "o", and "d" are in a dark red color, while "r" and "d" are in a lighter red color. Below the logo is the tagline "The Evolution of Generics" in a smaller, dark red font.

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