



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level Recall

Date: 13 February 2019

EL (19) A04

Our Ref: MDR 94-06/18

Dear Healthcare Professional,

Actavis Group PTC EHF

Irbesartan 300mg Film-coated tablets, PL 30306/0108

Batch Number	Expiry Date	Pack Size	First Distributed
191018	05/2020	1 x 28	30 Nov 2018
191118	05/2020	1 x 28	20 Dec 2018

Irbesartan / Hydrochlorothiazide 300 / 25mg Film-coated Tablets, PL 30306/0267

Batch Number	Expiry Date	Pack Size	First Distributed
263918	06/2020	1 x 28	21 Nov 2018

Actavis Group PTC EHF is recalling the above batches from pharmacies as a precautionary measure due to possible contamination with N-nitrosodiethylamine (NDEA).

Healthcare Professionals and wholesalers

- Stop supplying the batches listed above immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- If you receive queries about this issue from patients, advise them not to stop taking their medication as the health risk of discontinuing the medicine is higher than the potential risk presented by the contaminant. A treatment review is not necessary until the next routine appointment.
- We do not anticipate any shortages of Irbesartan containing products. It is possible, however, that there may be some local supply issues, in which case patients should be advised to speak to their doctor to discuss alternative treatments.

The MHRA continues to thoroughly investigate the issue alongside the European Medicines Agency (EMA) and the European Directorate for the Quality of Medicines (EDQM). We will continue to monitor the situation in the UK and consider what actions are necessary to protect public health.



Company contacts for further information

- For Actavis (now Accord) stock control: Customer Services Team on 0800 373573
- For medical information enquires please contact Accord Medical Information on 01271 385257

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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