Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level Recall

Date: 24 January 2019 EL (19)A/02 Our Ref: MDR 94-06/18

Dear Healthcare Professional,

Macleods Pharma UK Limited

Irbesartan 150mg Film-coated tablets, PL 34771/0079

Batch Number	Expiry Date	Pack Size	First Distributed
EIZ807A	July 2021	1 x 28	21 Nov 2018

Irbesartan 300mg Film-coated tablets, PL 34771/0080

Batch Number	Expiry Date	Pack Size	First Distributed
EIA1813A	July 2021	1 x 28	31 Oct 2018
EIA1811A	July 2021	1 x 28	31 Oct 2018

Macleods Pharma UK Limited 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 above 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 to continue 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 stock control enquiries and medical information enquiries, please contact eusafety@macleodspharma.com or telephone 01740 661110

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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