

# Public Health Link

From the Chief Medical Officer for Wales

<b>Distribution:</b>	As Annex 1
<b>From:</b>	Andrew Evans, Directorate of Health Policy
<b>Date:</b>	25 January 2019
<b>Reference:</b>	CEM/CPhA/2019/2
<b>Category:</b>	Class 2 – Action within 48 Hours
<b>Title:</b>	Drug Alert Class 2, Action Within 48 Hours, Macleods Pharma Uk Limited. Irbesartan 150mg Film-Coated Tablets And Irbesartan 300mg Film-Coated Tablets
<b>For Action by:</b>	All Dispensing General Practitioners - please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'.  All Community Pharmacists
<b>For Information:</b>	See Annex 1 – Distribution List
<b>What is this about:</b>	Full details are set out below.
<b>Why has it been sent:</b>	For your action and information and to pass on to Colleagues as appropriate.

**Issue:**

Recall of affected batches due to potential contamination with N-nitrosodiethylamine (NDEA).

Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website <https://www.gov.uk/drug-device-alerts>

**Distribution List**

To: NHS Wales Shared Services Partnership to forward to:

All Dispensing General Practitioners - please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'.

All Community Pharmacists

Deputising services

HB Chief Pharmacists

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

Community Optometrists

Chief Executives of Health Boards

Medical Directors of Health Boards

Nurse Directors Health Boards

Directors of Public Health

Hospital Principals and Chief Pharmacists to action as per alert

Public Health Wales

Consultants in Pharmaceutical Public Health

Chief Executives, NHS Trusts

Principal Pharmacist Welsh Quality Control

Principal Pharmacist Continuing Care Services

Principal Pharmacist Welsh Medicines Information Centre

CSSIW

NHS Direct



## 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.



**Medicines & Healthcare products  
Regulatory Agency**



**Company contacts for further information**

For stock control enquiries and medical information enquiries, please contact [esusafety@macleodspharma.com](mailto:esusafety@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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