

Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Annex 1
From:	Andrew Evans, Directorate of Health Policy
Date:	03 January 2019
Reference:	CEM/CPhA/2019/1
Category:	Class 2 – Action within 48 Hours
Title:	Drug Alert Class 2, Action Within 48 Hours, Actavis Group Ptc Ehf, Irbesartan /Hydrochlorothiazide 300 / 12.5mg Film-Coated Tablets; Irbesartan / Hydrochlorothiazide 150 / 12.5mg Film-Coated Tablets
For Action by:	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
For Information:	See Annex 1 – Distribution List
What is this about:	Full details are set out below.
Why has it been sent:	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: 03/01/2019

EL (19) A/01

Our Ref: MDR 94-06/18

Dear Healthcare Professional,

Actavis Group PTC EHF

Irbesartan / Hydrochlorothiazide 300 / 12.5mg Film-coated Tablets, PL 30306/0266

Batch Number	Expiry Date	Pack Size	First Distributed
059118	31/03/2020	1 x 28	17/09/2018
099218	31/03/2020	1 x 28	04/10/2018
191418	31/05/2020	1 x 28	25/10/2018

Irbesartan / Hydrochlorothiazide 150 / 12.5mg Film-coated Tablets, PL 30306/0265

Batch Number	Expiry Date	Pack Size	First Distributed
150118	30/04/2020	1 x 28	12/09/2018

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 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 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.

This is a developing issue and the MHRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact. An investigation into other potentially impacted products is continuing and further updates will be provided as the investigation progresses.



**Medicines & Healthcare products
Regulatory Agency**



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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