Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

T: 0131-244-2528
E: irene.fazakerley@gov.scot

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

22 August 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 4 DRUG ALERT 29 2023 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – ACCORD HEALTHCARE LTD,UK OLMESARTAN MEDOXOMIL 10 MG FILM COATED TABLETS

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- Dental Practitioners
- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

INVESTOR IN PEOPLE
POSITIVE ABOUT DISABLED PEOPLE

Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Pharmacy/Wholesaler Level/dispensing GP

Date: 22 August 2023 EL (23)A/29 Our Ref: MDR 103-08/23

Dear Healthcare Professional,

Accord Healthcare Limited, UK

Olmesartan Medoxomil 10mg film coated tablets **PL 20075/0238**

SNOMED Code: 34969911000001108

Batch No	Expiry Date	Pack Size	First Distributed
M2213437	08/2025	2X14T	28/06/2023
M2213708	08/2025	2X14T	09/05/2023
M2213819	08/2025	2X14T	31/03/2023
M2303226	04/2026	2X14T	16/05/2023

Active Pharmaceutical Ingredient: Olmesartan Medoxomil

Olmesartan Medoxomil 20mg film coated tablets **PL 20075/0239**

SNOMED Code: 34970211000001102

Batch No	Expiry Date	Pack Size	First Distributed
M2203689	02/2025	2X14T	31/01/2023

Active Pharmaceutical Ingredient: Olmesartan Medoxomil

Brief description of the problem

Accord Healthcare Ltd, UK has informed the MHRA about an error with the Patient Information Leaflets (PILs) that have been packaged in the above batches of these products. The PIL does not include the most up to date safety information regarding the signs and symptoms of liver issues and the need to seek medical advice if they occur. The information missing from the PILs is included below:

The information missing in the PIL is as follows:

"Section 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they do occur, they are often mild and do not require treatment to be stopped.

Although not many people may get them, the following side effects can be serious:
If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Olmesartan Medoxomil a longer time ago, contact your doctor immediately who will evaluate your symptoms and decide on how to continue your blood pressure medication."

Medicines & Healthcare products Regulatory Agency

Advice for healthcare professionals

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the product and where possible, provide an updated PIL. The updated PIL is available electronically and can be downloaded from the Accord website link below:

https://www.accord-healthcare-products.co.uk/document/pil-olmesartan-medoxomil-10mg-20mg-40mg-film-coated-tablets

If it is not possible to provide an updated PIL please advise patients of the missing information and the need to seek medical advice if these signs or symptoms occur.

Advice for patients

This issue is about missing information on the Patient Information Leaflets (PILs) in specific batches of Olmesartan Medoxomil tables for high blood pressure. The medicine itself is not affected and therefore patients do not need to take any action.

There have been some reports of liver problems in patients taking this medicine, but these do not happen to all patients. If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Olmesartan Medoxomil a long time ago, contact your doctor immediately.

These products will have been prescribed and dispensed by the qualified healthcare professional(s) responsible for your care. Patients should continue to take medicines from these batches as prescribed by your healthcare professional. If you have any concerns, please speak with your pharmacy team in the first instance.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information

For medical information enquiries please contact:

Accord Medical Information Department on 01271 385257, email- medinfo@accord-healthcare.com

For stock control enquiries please contact: Accord- Customer Services Team on 0800 373573

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Reporting of side effects
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574

Medicines & Healthcare products Regulatory Agency

DMRC@mhra.gov.uk