Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT NOTIFICATION, EL(25)A/37

Caution in Use

Issued 31 July 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Jubilant Pharmaceuticals NV

MEDICINE DETAILS

Olmesartan medoxomil 10mg film-coated tablets
Licence: PL 19156/0097
Active Ingredient: olmesartan medoxomil
SNOMED code: 4623911000001104
GTIN: 08902805202806

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
MR124001A	03/2026	28 tab/pack	02/10/2024
MR124002A	03/2026	28 tab/pack	30/09/2024

MEDICINE DETAILS

Olmesartan medoxomil 20mg film-coated tablets

PL 19156/0098

Active Ingredient: olmesartan medoxomil

SNOMED code: 4624211000001106

GTIN: 08902805202813

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
MR224001A	04/2026	28 tab/pack	02/10/2024

Background

Jubilant Pharmaceuticals NV has informed the MHRA that the Patient Information leaflet (PIL) in the cartons for the batches listed in this notification include an outdated PIL. These packs contain a PIL which was revised in September 2021. The latest approved PIL is dated January 2024.

The out-of-date PIL included in the affected batches is missing important updated safety information. The latest PIL is available on the MHRA website; the missing information relates to the following text that has been added into the PIL:

4. Possible side effects

Frequency not known: If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Olmesartan medoxomil film-coated tablets longer time ago, contact your doctor immediately who will evaluate your symptoms and decide on how to continue your blood pressure medication.

Advice for Healthcare Professionals:

Healthcare professionals are advised to review the information contained within this notification and take this into account when prescribing this product. When products from batches included in the table are supplied or dispensed, please ensure that patients are aware of the missing information. Please inform the patients that the latest PIL for olmesartan medoxomil film-coated tablets is available on the MHRA website. Alternatively, hard copies of the correct PIL will be provided by the Marketing Authorisation Holder upon request, so that any of the affected packs remaining in the dispensary can be supplemented with the correct PIL.

Jubilant can provide printed copy of an updated PIL to HCP's via safety.uk@lambda-cro.com, or telephone 0800 0668348.

Advice for Patients:

Patients should continue to take medicines from the impacted batch as prescribed by your healthcare professional. This does not affect the quality of the product. There is updated safety information in the latest patient information leaflet (PIL) which accompanies the medicine. The latest version of the PIL is available on the MHRA website:

The current PIL is missing some information which is presented below:

4. Possible side effects

Frequency not known: If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Olmesartan medoxomil film-coated tablets longer time ago, contact your doctor immediately who will evaluate your symptoms and decide on how to continue your blood pressure medication.

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.

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.

Additional information:

For medical information enquiries please email safety.uk@lambda-cro.com, or telephone 0800 0668348.

For stock control enquiries please email JPUK.Customerservice@jubl.com, or telephone 01233 552293

Recipients of this Medicines Notification 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.

Yours faithfully

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