

# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/50

### Caution In Use

Issued 25 November 2025

Distribute to Pharmacy/Wholesaler Level

#### MARKETING AUTHORISATION HOLDER (MAH)

Lexon UK Ltd

#### MEDICINE DETAILS

**Moclobemide 150mg tablets**

PLPI: **15184/1476**

Active Ingredient: **Moclobemide**

SNOMED code: **42274911000001106**

GTIN: **05037015030871**

#### AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
I3602	30/09/2027	30	11/02/2025
H4610	31/05/2029	30	23/09/2025

## Background

Lexon UK Ltd has informed the MHRA that the Patient Information Leaflet (PIL) in the cartons for the batches listed in this notification is missing important updated safety information.

Lexon UK Ltd has confirmed that 326 packs of the affected batches are already distributed in the market. The missing information from the PIL is detailed in this notification:

### 2. What you need to know before you take Moclobemide

In the section, "Take special care with Moclobemide", "Check with your doctor or pharmacist before taking Moclobemide if:"

You require pain relief with buprenorphine. The use of buprenorphine together with Moclobemide can lead to serotonin syndrome, a potentially life-threatening condition (see "Possible side effects").

The addition of Buprenorphine in the section "Do not take Moclobemide, and tell your doctor or pharmacist if you are taking the following"

### 4. Under Rare side effects (affects 1 in 10,000 people)

Serotonin syndrome, you may experience symptoms such as involuntary, rhythmic contraction of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature of above 38°C, irregular heartbeat, losing consciousness or having fits (seizures). Contact your doctor when experiencing such symptoms.

#### Advice for Healthcare Professionals:

There is no risk to product quality or impact to safety of the medicines listed in this notification because of this missing information. Healthcare professionals are advised to review the information contained within this notification and take this into account when dispensing this product, especially for new patients.

If the medicine listed in this notification are dispensed, ensure that patients are aware of the missing information. Please see [updated PIL](#) for the correct information.

Upon request, Lexon UK Ltd will provide hard copies of the updated PIL to pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information. To request hard copies of the PIL, please contact Lexon UK Ltd with your details, i.e. address, product with batch details, required number of leaflets.

#### Advice for Healthcare Professionals to Provide to Patients:

Patients should be aware that packs of Moclobemide 150mg Tablets, Batches **I3602** and **H4610**, contain the incorrect Patient Information Leaflet (PIL). The missing safety

information is listed in this notification and if you have any additional concerns relating to this information, please contact your pharmacist or prescriber.

The missing information, summarised in this notification, does not change or affect the quality of the product. Patients can continue to safely take this medicine unless they have concerns related to the missing information.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

### **Additional information:**

For all medical information enquiries and information on this product, please email [QA@lexonuk.com](mailto:QA@lexonuk.com), or telephone 01527 505 414.

For stock control enquiries please email [QA@lexonuk.com](mailto:QA@lexonuk.com), or telephone 01527 505 414.

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.

Yours faithfully

**Defective Medicines Report Centre**  
**10 South Colonnade**  
**Canary Wharf**  
**London**  
**E14 4PU**

**Telephone +44 (0)20 3080 6574**

[DMRC@mhra.gov.uk](mailto:DMRC@mhra.gov.uk)