



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 04 December 2024

EL (24)A/61

Our Ref: DMRC-34033472

Dear Healthcare Professional,

Brillpharma Limited

Oxybutynin hydrochloride Brillpharma 2.5 mg/5 ml Oral Solution

PL 40496/0009

SNOMED Code: 38072711000001102

Batch No	Expiry Date	Pack Size	First Distributed
OXY23001	Jul/2026	150 mL	30 April 2024

Active Pharmaceutical Ingredient: oxybutynin hydrochloride

Brief description of the problem

L M Manufacturing Limited has informed the MHRA that the patient information leaflet (PIL) in the cartons for the batch listed in the table above for Oxybutynin hydrochloride Brillpharma 2.5 mg/5 ml Oral Solution include an out of date PIL, dated July 2021. The latest PIL was authorised in 2023.

The out of date PIL from 2021 is missing information related to the following sections “What you need to know before you take Oxybutynin hydrochloride Brillpharma”; “Warnings and Precautions”; “In particular tell your doctor if you are taking any of the following”; “Pregnancy, breast-feeding and fertility”; “Not known: cannot be estimated from the available data”. The latest PIL, authorised in 2023, includes updated information related to the sections mentioned above.

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 Oxybutynin hydrochloride Brillpharma 2.5 mg/5 ml Oral Solution. When product from batch included in the table is supplied or dispensed, please ensure that patients are aware of the missing information. The electronic versions of the PIL is up to date and can be accessed via the following link:

<https://www.medicines.org.uk/emc/files/pil.13841.pdf>

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 are warnings in the updated patient information leaflet (PIL) which accompanies the medicine, for “What you need to know before you take Oxybutynin hydrochloride Brillpharma”; “Warnings and Precautions”; “In particular tell your doctor if you



Medicines & Healthcare products Regulatory Agency

are taking any of the following”; “Pregnancy, breast-feeding and fertility”; “Not known: cannot be estimated from the available data”). The updated PIL can be accessed via the following link:

<https://www.medicines.org.uk/emc/files/pil.13841.pdf>

If you have any concerns about the information provided with your medicine, please speak with your pharmacy team in the first instance. If you have concerns about a medicine, you may be using, please contact your healthcare professional.

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 info@brillpharma.co.uk.

For stock control enquiries please contact Telephone +44 (0) 1582 545500

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