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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

9 January 2025

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 – No 1 2025 – CLASS 4 MEDICINES DEFECT INFORMATION –
CAUTION IN USE – BRISTOL LABORATORIES LTD – RABEPRAZOLE SODIUM 10MG
GASTRO-RESISTANT 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:-

- 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



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 09 January 2025

EL (25)A/01

Our Ref: DMRC-33946703

Dear Healthcare Professional,

Bristol Laboratories Limited

Rabeprazole sodium 10mg gastro-resistant tablets

PL 17907/0457

SNOMED Code: 36601411000001106

Batch No	Expiry Date	Pack Size	First Distributed
LC72047	10/2025	28	4 September 2023
LC74744	02/2026	28	18 October 2023
LC76888	05/2026	28	30 September 2024

Rabeprazole sodium 20mg gastro-resistant Tablets

PL 17907/0458

SNOMED Code: 36601611000001109

Batch No	Expiry Date	Pack Size	First Distributed
LC72045	12/2025	28	8 March 2023
LC75526	05/2026	28	24 August 2023
LC76906	08/2026	28	30 September 2024

Active Pharmaceutical Ingredient: rabeprazole sodium

Brief description of the problem

Bristol Laboratories Limited has informed the MHRA that the Patient Information Leaflet (PIL) in the above specified batches of Rabeprazole sodium 10 mg gastro-resistant tablets and Rabeprazole sodium 20 mg gastro-resistant tablets do not contain the most up to date safety information. The affected sections of the PIL are summarized in the table below:

Section 2	What you need to know before you take Rabeprazole Sodium	Do not take Rabeprazole Sodium
		Warnings & Precautions
		Children
		Other medicines and Rabeprazole Sodium
		Pregnancy and breastfeeding
Section 3	How to take Rabeprazole sodium	Driving and using machines
		Taking the Medicines
		If you forget to take Rabeprazole sodium
Section 4	Possible Side Effects	Stop taking this medicine
		Other possible side effects Common (affect less than 1 in 1000)



Medicines & Healthcare products Regulatory Agency

		Other possible side effects (affect less than 1 in 100 people)
		Other possible side effects Rare (may affect up to 1 in 1000 people)
		Other possible side effects (unknown frequency)
		Reporting of side effects

Advice for healthcare professionals

The quality of medicine has not been affected, therefore, the affected batches are not being recalled.

Healthcare professionals are advised to ensure that the patients are aware of the updated safety information when dispensing the affected batches of product. Please provide a copy of the updated PIL and remind the patient to read the entire leaflet before taking the medicine. The electronic version of the PIL is up to date and can be accessed via the following links:

Rabeprazole sodium 10mg gastro-resistant tablets:

<https://mhraproducts4853.blob.core.windows.net/docs/7461ff7bf90349cf1f26c3bead3b723461eb1298>

Rabeprazole sodium 20mg gastro-resistant Tablets:

<https://mhraproducts4853.blob.core.windows.net/docs/107dab5a7bbae6cd91a6ce3997bfac76dafb40a7>

Advice for patients

The quality of medicine has not been affected, therefore patients do not need to take any action. Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

Patients should be aware that the Patient Information Leaflet (PIL) included in the packs of the above specified batches of medicines does not contain the most up to date safety information. The affected sections of the PIL are included in the table under 'Brief description of the problem'. The up-to-date version of the Patient Information Leaflet can be accessed via the links below. Please read this before taking the medicine.

Rabeprazole sodium 10mg gastro-resistant tablets:

<https://mhraproducts4853.blob.core.windows.net/docs/7461ff7bf90349cf1f26c3bead3b723461eb1298>

Rabeprazole sodium 20mg gastro-resistant Tablets:

<https://mhraproducts4853.blob.core.windows.net/docs/107dab5a7bbae6cd91a6ce3997bfac76dafb40a7>

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 at: email: info@bristol-labs.co.uk, or telephone: +44 (0) 1442 200 922

For stock control enquiries please contact at email: notifications@bristol-labs.co.uk, or telephone: +44 (0) 1442 200 922

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.



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Yours faithfully

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