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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

4 January 2024

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 DRUG ALERT 1 2024 – CLASS 4 MEDICINES DEFECT
INFORMATION – CAUTION IN USE – QUADRANT PHARMACEUTICALS LTD –
COZAAR 100MG 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:-

- 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: 04 January 2024

EL (24)A/01

Our Ref: MDR 197-11/23

Dear Healthcare Professional,

Quadrant Pharmaceuticals Ltd

Cozaar 100mg film-coated tablets

PLPI 20774/1830

SNOMED Code: N/A

Batch No	Expiry Date	Pack Size	First Distributed
6016W	31/08/2025	28	08/11/2023
5584W	31/08/2025	28	23/10/2023
5393W	31/08/2025	28	18/10/2023
5474W	31/08/2025	28	18/10/2023
5169W	31/03/2025	28	11/10/2023
5164W	30/06/2025	28	10/10/2023
5171W	31/08/2025	28	06/10/2023

Active Pharmaceutical Ingredient: Losartan Potassium

Brief description of the problem

Quadrant Pharmaceuticals Ltd has informed the MHRA of an error with the Patient Information Leaflets (PILs) that have been packed in the listed batches of Cozaar 100mg film-coated tablets. The PIL does not include the most up to date safety information as described below. In Section 2 'What you need to know before you take Cozaar', sub section 'Cozaar with food and drink' the following information is missing: **'Grapefruit juice should be avoided while taking Cozaar.'**

Advice for healthcare professionals

There is no risk to product quality because of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the products and where possible, provide an updated PIL.

The updated PIL is available here: <https://www.medicines.org.uk/emc/product/7798/pil> or by contacting licensing@maxearn.co.uk

If it is not possible to provide an updated PIL please advise patients of the missing information and discuss with them whether the medicine is suitable for them. Quadrant Pharmaceuticals Ltd has confirmed that all future imported batches will contain the correct PIL.

Upon request, Quadrant Pharmaceuticals Ltd will post hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information.



Medicines & Healthcare products Regulatory Agency

Advice for patients

Patients should continue to take medicines from these batches as prescribed by your healthcare professional. Patients are advised that grapefruit juice should be avoided while taking Cozaar.

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 licensing@maxearn.co.uk

For stock control enquiries please contact licensing@maxearn.co.uk

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

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