Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

T: 0131-244-2528
E: irene.fazakerley@gov.scot

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

7 April 2025

Dear Healthcare Professional,

DRUG ALERT CLASS 4 – No 15 2025 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – RENACARE NEPHROMED GMBH – RENACET 475MG AND 950MG TABLETS CALCIUM ACETATE

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 & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/15

Caution In Use

Issued 07 April 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

RenaCare NephroMed GmbH

MEDICINE DETAILS

Renacet 475 mg, film-coated tablets

PL: 36032/0001

Active Ingredient: Calcium Acetate

SNOMED code: 18613411000001100

GTIN: 4027052102120

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
2122403	30/06/2027	200	30/01/2025
2122404	30/06/2027	200	05/03/2025
2122405	30/06/2027	200	Not yet distributed
2122407	31/08/2027	200	Not yet distributed
2122408	31/08/2027	200	Not yet distributed
2122409	31/08/2027	200	Not yet distributed
2122410	31/08/2027	200	Not yet distributed

MEDICINE DETAILS

Renacet 950 mg, film-coated tablets
PL: 36032/0002
Active Ingredient: Calcium Acetate
SNOMED code: 18613911000001108
GTIN: 4027052102229

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
2222418	30/04/2027	200	11/02/2025
2222419	30/04/2027	200	07/03/2025
2222420	30/04/2027	200	27/03/2025
2222421	30/04/2027	200	Not yet distributed
2222422	30/04/2027	200	Not yet distributed
2222439	31/07/2027	200	Not yet distributed
2222440	31/07/2027	200	Not yet distributed
2222441	31/07/2027	200	Not yet distributed
2222442	31/07/2027	200	Not yet distributed
2222443	31/07/2027	200	Not yet distributed
2222444	31/07/2027	200	Not yet distributed
2222445	31/07/2027	200	Not yet distributed
2222446	31/07/2027	200	Not yet distributed
2222447	31/07/2027	200	Not yet distributed

Background

RenaCare NephroMed GmbH has informed the MHRA of the presence of an undeclared excipient in the coating of the tablets. This excipient is Macrogol 6000 which is included in Renacet tablets. Macrogol 6000 has always been included in Renacet Tablets but has been omitted from the list of excipients in error.

The batches listed as ‘not yet distributed’ have also been manufactured and packed with macrogol 6000. The MHRA, in discussion with the Department of Health and Social Care, considers these products critical for patients, therefore these batches will not be repackaged and continue to be distributed. They are therefore included in the notification.

Advice for Healthcare Professionals:

There has not been a change to the formulation of Renacet Tablets, prescribers should continue to provide these tablets to patients.

In very rare cases there are patients who are allergic to polyethylene glycols, with the possibility of minor allergic type reactions seen in patients who consume these ingredients orally. There have been very few reported adverse events associated with Renacet Tablets and the risk to patient health is minimal regarding this omission.

Macrogols are used in a range of pharmaceutical products as an excipient and at much higher doses, Macrogol is approved as a laxative in the UK at much higher quantities than are present in Renacet Tablets. This dose is far in excess of the dose consumed by patients who take Renacet as regular treatment.

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to take tablets from these batches as prescribed by your healthcare professional.

If you are taking Renacet Tablets and have an allergy to Macrogol or to polyethylene glycol please notify your prescribing doctor.

In very rare cases oral macrogol or polyethylene glycols may cause allergic reactions. If you develop skin reactions including hives and itching, wheezing, a new cough, or nausea and vomiting please inform your doctor as soon as possible.

Any suspected adverse reactions should also be reported online via the Yellow Card scheme or via the Yellow card app available from the Apple App Store or Google Play Store.

Additional information:

For medical information enquiries please telephone 01159 124 253 or email medinfo@stanningleypharma.co.uk .

For stock control enquiries telephone 01159 124 253 or email medinfo@stanningleypharma.co.uk

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.