Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

T: 0131-244-2528
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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

13 July 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 4 DRUG ALERT 24 2023 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – CIPLA (EU) LTD UK – SEREFLO CIPHALER 50MCG/250MCG/ DOSE INHALATION POWDER, PRE-DISPENSED BP

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:-

- Dental Practitioners
- 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

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Pharmacy/Wholesaler Level

Date: 13 July 2023 EL (23)A/24 Our Ref: MDR 002-07/23 & 024-05/23

Dear Healthcare Professional,

Cipla (EU) Limited, UK

Sereflo Ciphaler 50 microgram/250 microgram/dose Inhalation powder, Pre-Dispensed BP — PL 36390/0267

SNOMED Code: 40504911000001103

Batch Number	Expiry Date	Pack Size	First Distributed
ID12472	09/2023	1 x 60	15.02.2022

Active Pharmaceutical Ingredient: Fluticasone Propionate & Salmeterol xinafoate

Kelhale 50 micrograms per actuation pressurised inhalation solution — PLGB 36390/0319

SNOMED Code: 354301110000001100

Batch Number	Expiry Date	Pack Size	First Distributed
IB20103	11/2023	1 X 200 MD	27.05.2022
IB20104	11/2023	1 X 200 MD	27.05.2022
IB20105	11/2023	1 X 200 MD	27.05.2022
IB20532	03/2024	1 X 200 MD	15.09.2022

Active Pharmaceutical Ingredient: Beclometasone dipropionate anhydrous

Kelhale 100 micrograms per actuation pressurised inhalation solution — PLGB 36390/0320

SNOMED Code: 354303110000001103

Batch Number	Expiry Date	Pack Size	First Distributed
IB20106	11/2023	1 X 200 MD	23.06.2022
IB20107	11/2023	1 X 200 MD	30.05.2022
IB20108	11/2023	1 X 200 MD	01.07.2022
IB20543	03/2024	1 X 200 MD	25.11.2022
IB20544	03/2024	1 X 200 MD	13.09.2022
IB20545	03/2024	1 X 200 MD	13.09.2022
IB20546	03/2024	1 X 200 MD	15.09.2022
IB20547	03/2024	1 X 200 MD	20.09.2022
IB20548	03/2024	1 X 200 MD	31.10.2022

Active Pharmaceutical Ingredient: Beclometasone dipropionate anhydrous

Icatibant 30 mg solution for injection in pre-filled syringe **PLGB 36390/0285**

SNOMED Code: 41536211000001102

Batch Number	Expiry Date	Pack Size	First Distributed
IC0112246	01/2024	1 X 1's	30.07.2022

Active Pharmaceutical Ingredient: Icatibant

PHARMATHEN S.A.

Grepid 75 mg film coated tablets (Kent Pharma Livery) **PLGB 17277/0398**

SNOMED Code: 15907411000001101

Batch Number	Expiry Date	Pack Size	First Distributed
1206250	07/2025	28	04/08/2022
1206284	07/2025	28	04/08/2022
1206285	07/2025	28	04/08/2022
1206235	07/2025	28	04/08/2022
1206212	07/2025	28	04/08/2022
1206234	07/2025	28	04/08/2022
1206041	07/2025	28	04/08/2022
1206149	07/2025	28	04/08/2022
1206152	07/2025	28	04/08/2022
1206211	07/2025	28	04/08/2022

Active Pharmaceutical Ingredient: Clopidogrel

Brief description of the problem
Cipla (EU) Limited, UK has informed the MHRA that the outer carton (box) of the product batches mentioned in this notification are missing the medicines legal classification for a Prescription Only Medicine 'POM.'

Pharmathen S.A. has informed the MHRA that the outer carton (box) of some batches of Grepid 75 mg film coated tablets is missing the medicines legal classification for a Prescription Only Medicine 'POM.'

This only impacts the batches listed in this notification. Both Cipla (EU) Limited, UK and Pharmathen S.A. have confirmed that all future batches will include 'POM' on the outer carton (box). There is no impact to the product quality or safety and due to considerations, that these medicines are only supplied against a valid prescription, these batches are not being recalled.

Advice for healthcare professionals
Healthcare professionals are advised to exercise caution when handling the listed products and ensure that they are stored accordingly and in line with the guidance for the storage of Prescription Only Medicines (POM). Additionally, healthcare professionals are reminded to only dispense these products when the pharmacy team receives a suitable prescription prescribed by a qualified health professional.

Medicines & Healthcare products Regulatory Agency

Advice for patients
This issue is about missing information on the outer carton (box). The medicine itself is not affected and therefore patients do not need to take any action.

These products will have been prescribed and dispensed by the qualified healthcare professional(s) responsible for your care. If you have any concerns, 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 their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information

Cipla (UK) Limited

For more information regarding Cipla (EU) Limited, UK products, medical or supply enquiries, please contact telephone**:** +44 (0) 800 047 2144 or via email: drugsafety@Cipla.com & Uk.info@Cipla.com

Pharmathen S.A

For more information regarding Pharmathen S.A products, medical or supply enquiries, please contact telephone**:** +30 210 6604300 or via email: pharmacovigilance@pharmathen.com & info@pharmathen.com

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.

Yours faithfully

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London
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