



Department of  
**Health**

An Roinn Sláinte

Máinnystrie O Poustie

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**For Action:** Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO  
Heads of Pharmacy and Medicines Management of HSC Trusts  
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer  
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Our Ref: PHC/59/2020  
Date: 15 December 2020

## **DRUG ALERT**

### **CLASS 4 MEDICINES DEFECT INFORMATION**

**Caution in Use**

**Distribute to Pharmacy Level**

Dear Healthcare Professional

**Fairmed Healthcare GmbH**

**Co-Careldopa 25mg/100mg tablets**

**PL 20242/0028**

<b>Batch Number</b>	<b>Expiry Date</b>	<b>Pack Size</b>	<b>Market Release</b>
DT1912007A	30/11/2022	100	03/04/2020
DT1912006A	30/11/2022	100	03/04/2020
DT1910014B	30/09/2022	100	19/02/2020
DT1900015A	30/09/2022	100	19/02/2020
DRA07037A	30/06/2023	100	19/10/2020
DRA07036A	30/06/2023	100	04/09/2020
DRA01030A	31/12/2022	100	04/06/2020

Active pharmaceutical ingredients: carbidopa/levodopa

#### **Brief description of the problem**

Fairmed Healthcare GmbH has informed us of a discrepancy on the product packaging for the above batches. The discrepancy relates to the incorrect spelling of one of the active pharmaceutical ingredients printed on one side (end flap) of the packs in error. The incorrect end flap states that the active pharmaceutical ingredient is 'carbiopa' instead of 'carbidopa', (see Annex 1). The other product details on the pack including the name, strength and pharmaceutical form of the medicine are correct on all other sides of the carton.

#### **Advice for healthcare professionals**

Healthcare professionals are advised to exercise caution when dispensing the product. There is no risk to product quality as a result of this issue, therefore the associated batches are not being recalled at this time.

**Further Information**

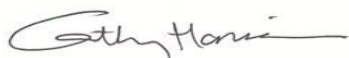
For more information or medical information queries, please contact: Fairmed Healthcare GmbH  
Dorotheenstraße 48, 22301 Hamburg, Germany, Quality Assurance Department or via email on QA  
Manager: [l.rozikova@fair-med.com](mailto:l.rozikova@fair-med.com)

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



Mrs Cathy Harrison  
Chief Pharmaceutical Officer

**Annex 1 – Packaging error (circled); incorrect spelling of active pharmaceutical ingredient  
See below**

N. 20247/0028



Fair-Med Healthcare GmbH  
Planckstr. 13  
Hamburg 22765  
Germany



**Co-Careldopa**  
**25 mg/100 mg**  
**tablets** [POM]  
carbidopa/levodopa

○  
**100** tablets  
Each white round tablet contains 25 mg carbidopa monohydrate and 100 mg levodopa.

**Co-Careldopa**  
**25 mg/100 mg**  
**tablets**  
carbidopa/levodopa

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

Medicinal product subject to medical prescription.

Oral use.

Read the package leaflet before use.

Keep out of the sight and reach of children.

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Each  
box  
contains  
100 tablets

**Co-Careldopa**  
**25 mg/100 mg**  
**tablets** [POM]  
carbidopa/levodopa

○  
**100** tablets  
Each white round tablet contains 25 mg carbidopa monohydrate and 100 mg levodopa.

