



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 15 December 2020

EL (20)A/59

Our Ref: MDR 017-07/20

Dear Healthcare Professional,

Fairmed Healthcare GmbH

Co-Careldopa 25mg/100mg tablets

PL 20242/0028

Batch Number	Expiry Date	Pack Size	Market Release
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



Recipients of this Drug Alert 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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574

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

