Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 04 December 2023 EL(23)A/40 Our Ref: MDR 217-10/23

Dear Healthcare Professional,

Teva UK Limited

Caramet 25/100mg CR Tablets **PL 00289/0924**

SNOMED Code: 11178911000001104

Batch Number	Expiry Date	Pack Size	First Distributed
23043965	Jan-2027	60 tablets	28 June 2023

Active Pharmaceutical Ingredient: Carbidopa (25mg) / Levodopa (100mg)

Brief description of the problem
Teva UK Limited, the Marketing Authorisation Holder (MAH) has informed the MHRA of a labelling error for the batch listed in this notification. The Active Pharmaceutical Ingredient (API) sequence incorrectly states levodopa/carbidopa on the carton (Figure 1), in the Patient Information Leaflet, and on the foil. The correct sequence should be carbidopa/levodopa (Figure 2), to be consistent with the actual API content within the tablets, which is 25mg Carbidopa and 100mg Levodopa.

Please see the images in the notification that indicate the incorrect and correct outer carton artwork. The PIL and foil packaging have not been included as the outer carton highlights the error.

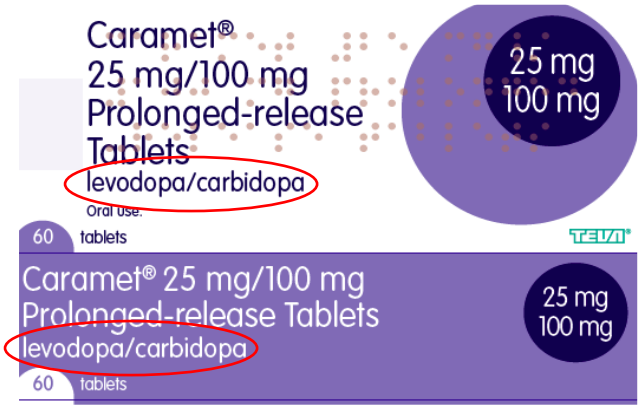

Figure 1 - incorrect artwork which states levodopa/carbidopa

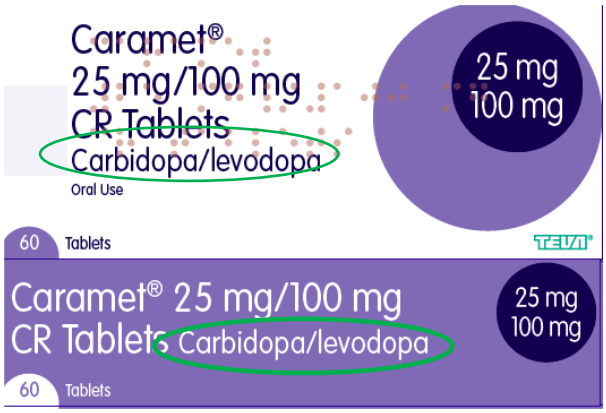

Figure 2 - correct artwork stating carbidopa/levodopa

Advice for healthcare professionals
There is no risk to product quality because of this issue, therefore the affected batch is not being recalled. Teva UK Limited have confirmed that the tablets in the pack for this batch contain 25mg Carbidopa and 100mg Levodopa.

Healthcare professionals, including those involved in prescribing and dispensing, are advised that the API content of batch 23043965 is 25mg Carbidopa/100mg Levodopa and not 25mg Levodopa/100mg Carbidopa as implied by the API text sequence on the packaging. **For this product, healthcare professionals should not prescribe or dispense additional levodopa to make up the required ratio of carbidopa to levodopa.**

This issue only affects batch 23043965, which consists of a total of 16,218 packs, the majority of which already been distributed. To avoid an out-of-stock situation for this product, distribution of the batch will continue until new supply with corrected artworks becomes available in early 2024.

Advice for patients
No further action is required by patients. If you receive or have received a pack from batch 23043965, please continue to take your medicine as prescribed by your doctor.

The dosage you require will have been carefully considered by your doctor, as such there is a low risk that your medicine was mis-prescribed.

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 the medication should seek medical attention.

Any suspected adverse reactions can also be reported via the MHRA Yellow Card scheme. Adverse events may also be reported to Teva UK Limited via email to medinfo@tevauk.com or via phone on +44 (0) 207 540 7117.

Further Information
For medical information queries, please contact: Teva UK Limited Medical Information via phone on 0207 540 7117 or via email: medinfo@tevauk.com

For stock control queries, please contact: Teva UK Limited Customer Solutions via phone on 0800 590502 or via email: Customer.services@tevauk.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
Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk