QD004-09 Appendix 1 Version 1

Drug Alert

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Date: 12.JAN.2021 Our Ref: MDR033-12/2020

Dear Pharmacist,

Boehringer Ingelheim Ltd c/o Vivian Corporation Ltd

Micardis 80mg tablets **EU/1/98/090/006**
(telmisartan)

Batch Number	Expiry Date	Pack Size	First Distributed
19J2401	03 2023	28 tabs	Nov 2019
20B0437	11 2023	28 tabs	-
20F0815	12 2023	28 tabs	-

The Medicines Authority has been informed by Boehringer Ingelheim (BI) Ltd, UK that there is an error on the Braille for the above batches.

The outer carton for Micardis 80mg Tablets (telmisartan) has been found to include the incorrect Braille information. Instead of 'Micardis 80mg' the Braille text incorrectly reads 'MicardisPlus 80mg'. All other aspects of the labelling (including visual labelling) are correct and the correct product (telmisartan 80mg tablets) is contained within the pack.

Due to the risk to visually impaired patients, in agreement with BI Ltd and Vivian Corporation Ltd, a Caution-In-Use letter is being distributed by Vivian Corporation Ltd to applicable pharmacies.

When dispensing packs from the affected batches referenced above, to patients with a visual impairment (or their carer), pharmacists are requested to notify the patient (or carer) of the labelling error in the Braille text.

Yours faithfully

Karl De Marco
Senior Medicines Inspector

Medicines Authority Distribution (if applicable):
Licensing Authority