

## DRUG ALERT

### CLASS 2 MEDICINES DEFECT INFORMATION

Action within 48 Hours

Distribute to Pharmacy and Clinic Level

Dear Healthcare Professional

#### Accord Healthcare Limited

##### Losartan Potassium 50mg Film-coated Tablets, PL 20075/0022

Batch number	Expiry Date	Pack Size	First Distributed
PT04882	Nov 2019	1 x 28	28/03/2018

##### Losartan Potassium 100mg Film-coated Tablets, PL 20075/0023

Batch number	Expiry Date	Pack size	First Distributed
PT02738	Jun 2019	1 x 28	27/02/2017
GX0135	Aug 2020	1 x 28	07/02/2019

Further to previous recalls of Valsartan and Irbesartan containing products, which were potentially contaminated with N-nitrosodimethylamine (NDMA) or N-nitrosodiethylamine (NDEA), we have become aware of products containing Losartan Potassium that are contaminated with a different nitrosamine, N-nitroso-N-methylamino butyric acid (NMBA).

Losartan Potassium containing products from Accord Healthcare Limited are affected and the batches listed above are being recalled.

#### Healthcare Professionals and Wholesalers

- Stop supplying the batches listed above immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- If you receive queries about this issue from patients, advise them to continue taking their medication as the health risk of discontinuing the medicine is higher than the potential risk presented by the contaminant. A treatment review is not necessary until the next routine appointment.



- We do not anticipate any shortages of Losartan Potassium containing products. In case of local supply issues, patients should be advised to speak to their doctor to discuss alternative treatments.

The MHRA continues to thoroughly investigate the issue alongside the European Medicines Agency (EMA) and the European Directorate for the Quality of Medicines (EDQM). We will continue to monitor the situation in the UK and consider what actions are necessary to protect public health

**Company Contacts for further information**

For stock control enquiries please contact Accord Customer Services on 0800 373573

For medical information enquiries please contact Accord Medical Information Department on 01271 385257

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

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.

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**TO ALL CHEMISTS, DOCTORS ON THE LISTS**

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**22<sup>nd</sup> March 2019**

Pharmaceutical website: <http://www.hscbusiness.hscni.net>