



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level Recall

Date: 21 March 2019

EL (19)A/07

Our Ref: MDR 94-06/18

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. NHS regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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