Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

M E D I C I N E S R E C A L L

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 05 May 2022 EL (22)A/21 Our Ref: MDR 009-03/22

Dear Healthcare Professional,

Pfizer Limited

Accupro 5 mg film-coated tablets PL 00057/0514

Batch Number	Expiry Date	Pack Size	First Distributed
FJ7218	31.05.2024	28	27th October 2021
EY5501	31.12.2022	28	2nd June 2021
EA9306	31.12.2022	28	10th November 2020

Accupro 10 mg film-coated tablets PL 00057/0515

Batch Number	Expiry Date	Pack Size	First Distributed
FK8588	30.06.2024	28	10th November 2021
EP6753	30.06.2023	28	23rd April 2021

Accupro 20 mg film-coated tablets PL 00057/0516

Batch Number	Expiry Date	Pack Size	First Distributed
FF8046	30.04.2024	28	22nd February 2022
FF8045	31.12.2022	28	7th October 2021
EA9304	30.09.2022	28	28th December 2020
DK4190	30.09.2022	28	7th April 2020

Accupro 40 mg film-coated tablets PL 00057/0517

Batch Number	Expiry Date	Pack Size	First Distributed
FK9758	30.04.2024	28	9th December 2021
EP1602	30.09.2022	28	21st April 2021
CW7390	30.09.2022	28	12th February 2020

Active Pharmaceutical Ingredient: Quinapril Hydrochloride

Brief description of the problem

Pfizer Ltd are voluntarily recalling all stock of the above product as a precautionary measure due to the identification of a nitrosamine above the acceptable limit. Following testing, N-nitroso-quinapril, has been observed at a level above the acceptable limit. Nitrosamines may increase the risk of cancer if people

are exposed to them above acceptable levels and over long periods of time. The recall is at pharmacy and wholesaler level.

Advice for healthcare professionals

Please quarantine all remaining stock of the specified batches and return them to your supplier using your supplier's approved process.

Patients should be advised not to stop any treatments without consulting their relevant healthcare professional. Based on the available data, there is no immediate risk to patients who have been taking this medication. Advise patients undergoing treatment not to discontinue Accupro without consulting with their prescriber, as there are potential risks associated with suddenly stopping treatment for blood pressure. Healthcare professionals should advise patients undergoing treatment to discuss any questions or concerns with their prescribing healthcare professional.

See additional advice from the Department of Health and Social Care

All healthcare professionals in primary and secondary care should:

- defer initiating any new patients on quinapril (Accupro®) tablets;
- identify affected patients and refer to local or national treatment guidelines to switch to an alternative ACE inhibitor
- monitor patients for changes in blood pressure and/or symptom control when prescribing alternative medications; and
- counsel patients on new medication, dose regime and potential side-effects.

Advice to patients

- We have asked pharmacists to stop supplying Accupro® tablets after they were found to have excess levels of a chemical impurity that may potentially increase the risk of cancers if taken for a long time
- Do not stop taking tablets for blood pressure without talking to your prescriber as there are potential risks associated with suddenly stopping treatment for blood pressure. Based on the available data, there is no immediate risk to patients who have been taking this medication.
- Your prescriber will review your blood pressure treatment and switch you from Accupro to a suitable alternative

Further Information

Pfizer is aware of the current supply constraints related to this product and is working to resolve the issue and resume manufacturing. Further updates relating to potential resupply will be communicated in due course. If you have any questions, then please contact your local Service Centre Customer Services team.

For medical information enquiries, please contact Pfizer Medical Information Department on 01304 616161.

Recipients of this Medicines Recall 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.

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