Pfizer issues a Voluntary Recall of Quinapril HCl (Accupril) 5 mg, 10 mg, 20 mg Tablets in the Philippines

MANILA, PHILIPINES, 11 May 2022 – Pfizer is voluntarily recalling Quinapril HCl (Accupril) tablets distributed by Pfizer at the retail level due to the presence of a nitrosamine, N-Nitroso-quinapril, above the acceptable intake limit. Pfizer is undertaking this as a precautionary measure.

Accupril is indicated for the treatment of hypertension as monotherapy or concomitantly with thiazide diuretics and beta-blockers in patients with hypertension, and for the treatment of congestive heart failure when given concomitantly with a diuretic and/or cardiac glycoside.

Everyone is exposed to some level of nitrosamines, which can be found in potable water, grilled foods, vegetables, and dairy products as well as medicines.[1] Regulatory authorities, including the US FDA have indicated that long-term ingestion of certain nitrosamines may be associated with a theoretical increased cancer risk in humans.[1] There is no immediate risk to patients taking this medication.

To date, Pfizer is not aware of any adverse events assessed to be related to this recall. We are continuing to monitor and report adverse events according to applicable regulatory authority requirements.

Pfizer understands the challenges that this situation poses to wholesalers, distributors, pharmacies, and patients. We fully realize the importance of this medicine to our customers. We are committed to ensuring the safety and quality of our medicines. There likely will be a period of supply interruption of Accupril tablets in Philippines. Until the situation is resolved, patients will need to consult with their healthcare professional to choose an alternate treatment option.

Pfizer has notified its distributors and retailers to arrange for the return of any recalled product.

Pfizer is voluntarily recalling the following lots of quinapril hydrochloride Accupril tablets at the retail level:

DESCRIPTION	LOT	EXPIRY	First Sale
ACCUPRIL 5mg FCT 4x14 BLS PH	FN6525	5/31/2024	21 February 2022
ACCUPRIL 5mg FCT 4x14 BLS PH	DM5044	12/31/2022	23 June 2020
ACCUPRIL 20mg FCT 4x14 BLS PH	EA9305	12/31/2022	19 February 2020

Should you have any questions regarding this recall, please contact Pfizer Product Quality via pcom-gophl@pfizer.com, Mon-Fri for assistance, or if you require additional medical information, please contact Pfizer Medical Information via www.pfizermedinfo.ph

[1] U.S. Food and Drug Administration. Control of Nitrosamine Impurities in Human Drugs Guidance for Industry. https://www.fda.gov/media/141720/download Accessed March 2022.

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