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Direct Healthcare Professional Communication

28 March 2022

Accuretic (quinapril hydrochloride and hydrochlorothiazide): recall of tablets due to presence of nitrosamines above the acceptable daily intake level – advice for prescribers on impact on patient treatment

Dear Healthcare Professional,

Pfizer, in agreement with Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the following:

Summary

- All Accuretic (quinapril hydrochloride and hydrochlorothiazide) tablets are being recalled at the pharmacy and wholesale level as a precautionary measure due to the observation of levels of N-nitroso-quinapril (an impurity) above the acceptable daily intake level.
- As a result of the recall, Accuretic will not be available to dispense from pharmacies. Currently no information can be provided for when Accuretic will be available again
- 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 Accuretic without consulting with their prescriber, as there are potential risks associated with suddenly stopping treatment for blood pressure. Patients should discuss any questions or concerns with a healthcare professional.
- For patients who are already taking Accuretic, it will not be possible to continue treatment and the prescribing healthcare professionals should review their hypertension treatment and switch patients to a suitable alternative.
- Prescribers should contact patients for a routine appointment and use their clinical judgement to determine the best alternative for their patient.
- As no Accuretic will be available, no new patients should be initiated on this treatment.

Background

Accuretic (10mg quinapril hydrochloride and 12.5mg hydrochlorothiazide) is authorised for the treatment of all grades of essential hypertension in patients who have been stabilised on the individual components given in the same proportions.

Test results have identified the levels of N-nitroso-quinapril in Accuretic to exceed the acceptable daily intake (ADI) level.

N-Nitroso-quinapril is a nitrosamine. Nitrosamines are classified as probable human carcinogens (substances that could cause cancer). Nitrosamines can be found in water and foods, including cured and grilled meats, dairy products, and vegetables. Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. As a precautionary measure, Pfizer Limited is (in agreement with MHRA) recalling all Accuretic (quinapril hydrochloride and hydrochlorothiazide) at the pharmacy and wholesale level.

Call for reporting

Please report suspected adverse drug reactions (ADRs) or suspected defective medicines to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website: https://yellowcard.mhra.gov.uk/
- the free Yellow Card app available from the Apple App Store or Google Play Store.
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Suspected adverse drug reactions may also be reported to Pfizer Medical Information on 01304 616161.

Company contact point

If you have any questions about this letter or for more information about Accuretic (quinapril hydrochloride and hydrochlorothiazide) please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616161

Yours sincerely,

Digitally signed by Berkeley Phillips
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Date: 2022.03.25 15:18:47 Z

Dr. Berkeley Phillips

Medical Director