

Direct Healthcare Professional Communication

5 May 2022

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

Summary

- All Accupro (quinapril hydrochloride) tablets are being recalled at the pharmacy and wholesale level as a precautionary measure due to the observation of levels of *N*-Nitroso-quinapril above the acceptable daily intake level.
- As a result of the recall, Accupro will not be available to dispense from pharmacies. Currently no information can be provided for when Accupro will be available again.
- *N*-Nitroso-quinapril is a nitrosamine specific to quinapril products.
- 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 or heart failure. Patients should discuss any questions or concerns with a healthcare professional.
- For patients who are already taking Accupro, it will not be possible to continue treatment and the prescribing healthcare professional should review patients' treatment and switch patients to a suitable alternative.
- Prescribers should contact patients and make a routine appointment with them to discuss the best alternative treatment for each patient, based on clinical judgement. As Accupro will not be available, no new patients should be initiated on this treatment.

Background

Accupro (5 mg, 10 mg, 20 mg and 40 mg quinapril) is authorised for the treatment of all grades of essential hypertension as monotherapy or concomitantly with diuretics in patients

with hypertension, and for the treatment of congestive heart failure when given concomitantly with a diuretic and/or cardiac glycoside.

Test results have identified the levels of *N*-Nitroso-quinapril in Accupro to exceed the acceptable daily intake (ADI).

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.

Nitrosamines may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. The risk for patients is considered to be low. Based on the available data, there is no immediate risk to patients who have been taking this medication.

As a precautionary measure, Pfizer Limited is (in agreement with MHRA) recalling all Accupro (quinapril hydrochloride) 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 timing, 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 require more information about Accupro (quinapril hydrochloride) please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616161

Yours sincerely,

Dr. Berkeley Phillips

UK Medical Director

Pfizer Ltd