

Dear Healthcare Professional.

Food and Drugs Authority

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FDA/SMC/SMD/VGU/17/0	16 th October 2017

ANGIOTENSIN CONVERTING ENZYME INHIBITOR-ASSOCIATED ANGIODEMA: HIGHER RISK IN PATIENTS OF AFRICAN DESCENT

The Food and Drugs Authority (FDA) has become aware of recent reports on social media which described Lisinopril and other Angiotensin Converting Enzyme (ACE) inhibitors as dangerous and deadly medicines and advised patients to stop taking these medicines because of increased risk of angioedema in patients of African descent.

Angioedema is swelling (oedema) caused by a build-up of fluid in deeper layers of the skin. It tends to affect areas with loose tissue, especially the face and throat, as well as the limbs and genitals. Angioedema may be mild, but if it progresses rapidly, or if it affects the throat, it can cause asphyxiation which requires emergency medical care.

The FDA wishes to remind healthcare professionals that angioedema is a known side effect of ACE inhibitors and studies have reported up to three-fold higher risk in patients of African descent compared to white patients. This side effect is also listed in the package insert and the FDA received 151 suspected adverse reaction reports of ACE inhibitor-associated angioedema out of the total of 4,618 adverse reaction reports received from 2005 to 2016 in which most of the patients fully recovered.

ACE inhibitors registered by the FDA are indicated for the control of high blood pressure, congestive heart failure, prevention of stroke, hypertension and diabetes-related kidney damage.

Below is the list of generic names of ACE inhibitor-containing drugs registered by the FDA:

- Lisinopril Tablets
- Captopril Tablets
- Enalapril Tablets
- Perindopril Tablets

¹ Buckhart DG, Brown NJ, Griffin MR, et al. Angiotensin converting enzyme-associated angioedema: higher risk in blacks than whites. Pharmacoepidemiol Drug Saf 1996; 5: 149–54

- Ramipril Tablets
- Fosinopril Tablets
- Enalapril and Hydrochlorothiazide Tablets
- Lisinopril and Hydrochlorothiazide Tablets
- Lisinopril and Amlodipine Tablets
- Ramipril and Hydrochlorothiazide Tablets
- Ramipril and Felodipine Tablets

The FDA will like to advice healthcare professionals to educate patients on the possible side effect of all medicines including ACE inhibitor-associated angioedema and report these to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh/ or call 024 431 0297 or send an email to drug.safety@fdaghana.gov.gh/.

Yours faithfully,

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