



FDA/SMC/SMD/VGU/18/0407

27th December 2018

Dear Healthcare Professional,

HYDROCHLOROTHIAZIDE AND THE RISK OF SKIN CANCER

The Food and Drugs Authority (FDA) wishes to bring to your attention a new information relating to two epidemiological studies^{1,2} which have shown an increased risk of non-melanoma skin cancer (basal cell carcinoma [BCC], squamous cell carcinoma [SCC]) with exposure to increasing cumulative doses of hydrochlorothiazide.

Based on the results of the two studies, the best estimate of the increased risk is 7.7-fold for SCC and 1.5-fold for BCC based on a length of usage of hydrochlorothiazide 12.5mg daily for 44 years or 25 mg daily for 22 years. For hypertension, products containing 25 mg of hydrochlorothiazide are indicated only if patients are not adequately controlled on lower-dose products.

Non-melanoma skin cancer is a rare event. Incidence rates highly depend on skin phenotypes and other factors, which leads to different baseline risks and varying incidence rates in different countries. The incidence rate for BCC in Africa is < 1/100,000 person-years³.

HCTZ-containing medicines are used to treat hypertension, as well as cardiac and hepatic oedema, or chronic heart insufficiency.

Healthcare professionals are therefore advised to take note of the following:

- Patients taking HCTZ-containing products should be informed about the risk of NMSC, particularly in long term use and advise to regularly check for (and report) any new or changed skin lesions or moles.
- Suspicious moles or skin lesions should be examined, potentially including histological examination of biopsies.
- Patients should be advised to limit exposure to sunlight and UV rays and use adequate protection when exposed to sunlight and UV rays to minimize the risk of skin cancer.

¹ Pedersen SA, et al. [Hydrochlorothiazide use and risk of non-melanoma skin cancer: A nationwide case-control study from Denmark](#). J Am Acad Dermatol 2018; 78: 673–81

² Pottegård A, et al. [Hydrochlorothiazide use is strongly associated with risk of lip cancer](#). J Intern Med 2017; 282: 322–31

³ Lomas A, et al. [A systematic review of worldwide incidence of nonmelanoma skin cancer](#). Br J Dermatol. 2012 May;166(5):1069-80.

- The use of HCTZ should be carefully reconsidered in patients who have had previous skin cancer.

The FDA will like to advice healthcare professionals to report adverse drug reactions to HCTZ-containing products and all other medicines 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,

Signed

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FOR: CHIEF EXECUTIVE OFFICER