August 25, 2020 **COM-2020-061**

DRUG SAFETY NOTIFICATION

DATE: August 20, 2020

DRUG NAME: Hydrochlorothiazide

SAFETY TOPIC: FDA approves label changes to describe small risk of non-melanoma skin cancer

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on August 20, 2020 the US Food and Drug Administration (FDA) published a safety communication for **Hydrocholorothiazide** indicating approval to changes in the label of the drug. Health care professional and patients should be aware of the small risk of non-melanoma skin cancer (either squamous cell or basal cell skin cancer).

Recommendations for healthcare professionals:

- Patients should continue their treatment with hydrochlorothiazide since the risk of holding treatment can be severe and a life-threatening heart attack or stroke may occur, unless otherwise directed from their health care provider.
- Advise patients to protect the skin from the sun and undergo regular skin cancer screening. In addition, patient can receive counseling about the use of sunscreen (at least 15 SPF) to be use on daily basis to protect the skin from sun exposure.
- Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:
  - Complete and submit the MedWatch Online Voluntary Reporting Form online.

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- Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2020). FDA approves label changes to hydrochlorothiazide to describe small risk of non-melanoma skin cancer. Retrieved from https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-label-changes-hydrochlorothiazide-describe-small-risk-non-melanoma-skin-cancer

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