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(來函請敘明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

19 May 2025

Dear Healthcare Professionals,

FDA requires warning about rare but severe itching after stopping long-term use of oral allergy medicines cetirizine or levocetirizine (Zyrtec, Xyzal, and other trade names)

Your attention is drawn to the US Food and Drug Administration (FDA)'s announcement that patients stopping the oral allergy medicines cetirizine (Zyrtec) or levocetirizine (Xyzal) after long-term use may experience rare but severe itching.

Cetirizine and levocetirizine are approved to treat seasonal allergic rhinitis, in adults and children 2 years and older, perennial allergic rhinitis, and chronic idiopathic urticaria, in patients 6 months and older.

These medicines are available in prescription and over-the-counter (OTC) forms. The itching, also called pruritus, has been reported in patients who used these medicines daily, typically for at least a few months and often for years. Patients did not experience itching before starting the medicines. Reported cases were rare but sometimes serious, with patients experiencing widespread, severe itching that required medical intervention. As a result, FDA is revising the prescription cetirizine and levocetirizine prescribing information to include a new warning about this risk. FDA will subsequently request that manufacturers add a warning about pruritus to the Drug Facts Label of the OTC versions.

FDA is adding a warning about the risk of pruritus after stopping long-term use of prescription cetirizine or levocetirizine to the prescribing information to increase awareness about this rare but serious reaction. The updated prescribing information also states that pruritus symptoms may improve with restarting the medicines. FDA will also request that manufacturers add a warning about pruritus to the Drug Facts Label of OTC cetirizine and levocetirizine. In the meantime, FDA want to make the public aware of this risk. FDA will follow up when additional information becomes available.

Health care professionals should discuss the risk of pruritus after stopping cetirizine or levocetirizine with patients when prescribing or recommending these medicines, especially if planned for chronic use, and with those who indicate they are using OTC versions. Encourage patients to contact you if they experience severe itching after stopping cetirizine or levocetirizine. Effective treatments for pruritus have not been evaluated. However, symptoms resolved in most patients who restarted the medicine and in some who tapered off the medicine after restarting it.

Please refer to the following website in FDA for details:
https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warning-about-rare-severe-itching-after-stopping-long-term-use-oral-allergy-medicines

In Hong Kong, there are 77 registered pharmaceutical products containing cetirizine and 24 registered pharmaceutical products containing levocetirizine. Five of the products are pharmacy only medicines and 96 of the products are over-the-counter medicines.

So far, the Department of Health (DH) has received 1 case of adverse drug reaction related to cetirizine but the case was not related to rare but severe itching after stopping long-term use of the product. The DH has not received any cases of adverse drug reaction related to levocetirizine.

In light of the above FDA's announcement, DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Vincent CHIANG)
for Assistant Director (Drug)