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DH DO PRIE/7-30/15  
(來函請敘明此檔案號碼)  
(IN REPLY PLEASE QUOTE THIS FILE REF.)

10 Dec 2020

Dear Healthcare Professionals,

**Clobazam-containing products: Assessing the potential risk of Drug Reaction with Eosinophilia and Systemic Symptoms**

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) with clobazam use after becoming aware of international case reports published in the medical literature. DRESS is a rare, but serious, and potentially life-threatening drug reaction that includes fever, severe skin rash or peeling of the skin over large areas of the body, swollen face and high white blood cell count, affecting 1 or more organs. The symptoms of DRESS typically appear within 2 weeks to 2 months after starting a medication. DRESS is also known as Drug Rash with Eosinophilia and Systemic Symptoms, Drug Induced Hypersensitivity Syndrome or DRESS syndrome.

Health Canada reviewed information provided by the manufacturers, data from clinical studies, information resulting from searches of the Canada Vigilance database, and the published literature. Health Canada's review focused on 2 Canadian cases and 18 international cases of DRESS in patients taking clobazam. From those cases, only 4 (international) met the criteria for further assessment to determine if there was a link between the use of clobazam and DRESS. Three of them were published in the medical literature and involved children. In all 4 cases, a link between clobazam use and DRESS could not be ruled out. Two cases were found to be probably linked to the use of clobazam. The 2 other cases were found to be possibly linked to clobazam use, however, these patients were also taking other medications that have been known to cause DRESS. There are no confirmed cases of DRESS in Canada associated with the use of clobazam.

Health Canada's review of the available information concluded that there may be a link between the use of clobazam and the potential risk of DRESS. Health Canada will work with the manufacturers to update the Canadian product safety information for clobazam-containing products to include the risk of DRESS.

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aspire to be an internationally renowned public health authority*

Please refer to the following website in Health Canada for details:

<https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00251>

In Hong Kong, there is one registered pharmaceutical product containing clobazam, namely Frisium 10 Tab 10mg (HK-05574). The product is registered by Sanofi Hong Kong Limited, and is a prescription-only medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to clobazam. In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. 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 Undesirable Medical Advertisements and Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: [adr@dh.gov.hk](mailto: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,



(Joseph LEE)

for Assistant Director (Drug)