

衛生署藥物辦公室
藥物資訊及警戒科

香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室



DEPARTMENT OF HEALTH
DRUG OFFICE

DRUG INFORMATION AND
PHARMACOVIGILANCE DIVISION

Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

電話號碼 Tel. No.: 3974 4175

詢問處 Enquiries: (852) 3974 4175

傳真號碼 Faxline No.: (852) 2803 4962

本署檔號 OUR REF.:

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

25 May 2022

Dear Healthcare Professionals,

Valacyclovir-containing products: Assessing the potential risk of drug reaction with eosinophilia and systemic symptoms (DRESS)

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 the use of valacyclovir-containing products. This safety review was triggered by updates made by the European Medicines Agency to the product safety information for valacyclovir-containing products to include the risk of DRESS.

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 one 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 manufacturer of the brand name product, and from searches of the Canada Vigilance database and the published literature. Health Canada reviewed 115 cases (3 Canadian, 112 international) of DRESS in patients taking valacyclovir. Of the 115 cases, 26 (international) met the criteria for further assessment to determine if there was a link between the use of valacyclovir and DRESS. Of the 26 case reports, 4 cases, including 3 published in the scientific literature, were found to be probably linked to the use of valacyclovir. Twenty-one cases, including 1 death, were found to be possibly linked, and 1 case was unlikely to be linked to the use of valacyclovir. In 25 of the 26 cases, patients were also taking other medications known to cause DRESS.

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

*We build a healthy Hong Kong and
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=SSR00284>

In Hong Kong, there are 12 registered pharmaceutical products containing valacyclovir. All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to valacyclovir. In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

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 Adverse Drug Reaction 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,



(Terence MAN)

for Assistant Director (Drug)