衞生署藥物辦公室
藥物資訊及進出口管制科
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
IMPORT/EXPORT CONTROL 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.: (852) 3974 4175
詢問處 Enquiries (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:

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

20 Dec 2024

Dear Healthcare Professionals,

Ilaris (canakinumab): 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 the use of Ilaris (canakinumab). The safety review was triggered by a labelling update by the European Medicines Agency and Health Canada's subsequent review of routine safety reports from the manufacturer of Ilaris.

Ilaris is a prescription drug belonging to a class of drugs called interleukin-1 (IL-1) inhibitors. It is authorized for sale in Canada for the treatment of various inflammatory conditions, including Still's disease, a rare type of inflammatory arthritis occurring in children as systemic juvenile idiopathic arthritis (sJIA) and in adults as adult-onset Still's disease.

Health Canada reviewed the available information provided by the manufacturer, and from searches of the Canada Vigilance database and the scientific literature. Health Canada reviewed 27 cases (1 Canadian and 26 international) of DRESS in patients taking Ilaris. Of those 27 cases, 4 were found to be possibly linked to the use of Ilaris, 5 (1 Canadian) were unlikely to be linked and 18 could not be assessed due to missing information. The 4 possible cases were reported in pediatric patients, 3 of whom were being treated for sJIA. One death was reported among the 4 possible cases. It is unclear whether DRESS was a contributing factor to the death.

Health Canada's review of the available information concluded that there is a possible link between the use of Ilaris and the risk of DRESS. Health Canada is working with the manufacturer to update the Canadian product monograph for Ilaris with a warning about reported cases of DRESS, predominantly

in patients with sJIA. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Please refer to the following website in Health Canada for details:
https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1732291653402

In Hong Kong, there is one registered pharmaceutical product containing canakinumab, namely Ilaris Solution For Injection 150mg/ml (HK-65635). The product is registered by Novartis Pharmaceuticals (HK) Limited. It is a prescription-only medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction with regard to canakinumab. 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 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,

p.p. (Terence MAN)
for Assistant Director (Drug)