

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.)

27 Oct 2022

Dear Healthcare Professionals,

EVUSHELD (tixagevimab and cilgavimab for injection) - Risk of prophylaxis or treatment failure due to antiviral resistance

Your attention is drawn to the Health Canada's announcement that Evusheld (tixagevimab and cilgavimab for injection) may not be effective against certain SARS-CoV-2 Omicron subvariants when used as a prophylaxis or treatment for COVID-19.

Healthcare professionals are advised to:

- Consider local epidemiology and individual exposure to circulating SARS-CoV-2 viral variants when making decisions regarding the use of Evusheld.
- Inform patients who receive Evusheld about the potential for a lack of effectiveness against certain SARS-CoV-2 viral variants. Instruct patients to seek medical advice if signs or symptoms of COVID-19 occur, persist or worsen.
- Refer to the Evusheld Canadian Product Monograph (CPM), in conjunction with the literature and local guidelines, for information regarding specific variants and antiviral resistance.

Circulating SARS-CoV-2 viral variants may be associated with resistance to monoclonal antibodies, such as Evusheld. The CPM for Evusheld has been updated to include new information about the risk of prophylaxis or treatment failure due to antiviral resistance, including neutralization data on SARS-CoV-2 Omicron subvariants.

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

<https://recalls-rappels.canada.ca/en/alert-recall/evusheld-tixagevimab-and-cilgavimab-injection-risk-prophylaxis-or-treatment-failure>

In Hong Kong, Evusheld Solution For Injection 150mg/1.5mL + 150mg/1.5mL (HK- 67457) is a pharmaceutical product registered by Astrazeneca Hong Kong Ltd. The product is a prescription-only medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to Evusheld. In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*

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)