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

19 January 2026

Dear Healthcare Professionals,

Alecensa® (alectinib): Guidance for Management of Severe Hypertriglyceridaemia

Your attention is drawn to the following Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Roche Singapore Pte. Ltd. to inform healthcare professionals that hypertriglyceridaemia, including severe and life-threatening events, has been identified as a new risk with Alecensa® (alectinib) based on cumulative data from clinical studies and postmarketing sources. Severe hypertriglyceridaemia is considered a medical emergency as it may lead to acute pancreatitis.

Healthcare professionals are advised to obtain baseline blood triglyceride measurements from patients before starting Alecensa® and periodically during treatment. Patients should be monitored for symptoms of acute pancreatitis, particularly those at increased risk. If severe or life-threatening triglyceride elevations occur, Alecensa® should be temporarily withheld until recovery to at least moderate hypertriglyceridaemia levels. Risk factors for pancreatitis should be evaluated, and treatable factors addressed before treatment initiation. Roche will be updating the product information to include this new risk and its associated recommendations.

Please refer to the following website in HSA for details:
http://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/alecensa--(alectinib)--guidance-for-management-of-severe-hypertriglyceridaemia

In Hong Kong, Alecensa Capsules 150mg (HK-64854) is an alectinib-containing pharmaceutical product registered by Roche Hong Kong Limited and is a prescription-only medicine. Alecensa is used for treatment of non-small cell lung cancer. So far, the Department of Health (DH) has received 26 cases of adverse drug reaction related to alectinib but none of them are related to hypertriglyceridaemia and acute pancreatitis. In light of the above HSA's announcement, the DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

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,

(Clive CHAN)
for Assistant Director (Drug)