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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.)

5 Sep 2025

Dear Healthcare Professionals,

Polivy (polatuzumab vedotin): New identified risk of severe infusion site extravasation events

Your attention is drawn to the following Singapore Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Roche Singapore Pte Ltd to update healthcare professionals on the new identified risk of infusion site extravasation with polatuzumab vedotin. Analysis of data from post marketing and clinical settings have provided sufficient evidence of a causal association of the events with polatuzumab vedotin.

Healthcare professionals are advised to ensure adequate venous access before initiating infusion and maintain close monitoring throughout administration for signs of extravasation. If extravasation is suspected, the infusion should be stopped immediately. The needle should be withdrawn following a brief aspiration and the affected limb elevated. Appropriate symptomatic management may be initiated as required. Roche will be updating the product label to reflect this risk.

Polivy in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) is indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL). Polivy in combination with bendamustine and MabThera is indicated for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for haematopoietic cell transplant.

Please refer to the following website in HSA for details:
https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/polivy-(polatuzumab-vedotin)--new-identified-risk-of-severe-infusion-site-extravasation-events

In Hong Kong, Polivy Powder For Concentrate For Solution For Infusion 140mg (HK-66664) and Polivy Powder For Concentrate For Solution For Infusion 30mg (HK-67107) are pharmaceutical

products registered by Roche Hong Kong Limited. They are prescription-only medicines. So far, with regard to polatuzumab vedotin, the Department of Health (DH) has received 29 cases of adverse drug reaction, but these cases were not reported as infusion site extravasation. The DH will remain vigilant on 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,

(Vincent CHIANG)
for Assistant Director (Drug)