

Singapore: Risk of severe haemorrhage with Cotellic™ (cobimetinib)

Singapore Health Sciences Authority (HSA) announced that Roche would like to inform healthcare professionals of the risk of severe haemorrhage associated with the use of Cotellic™ (cobimetinib).

Haemorrhage is a known adverse drug reaction of Cotellic™. An analysis on post-marketing safety reports and ongoing clinical trials has identified additional severe haemorrhage events in patients receiving Cotellic™, including intracranial and gastrointestinal tract bleeds. In most cases of severe haemorrhage, the patients had additional risk factors for bleeding, such as central nervous system metastasis, pre-existing gastrointestinal disorders, and/or concomitant medications that increase the risk of bleeding, such as antiplatelet or anticoagulant therapy.

Healthcare professionals are advised to take into consideration the above safety information when prescribing Cotellic™, and to discuss the risks that may be associated with Cotellic™ therapy with patients and their caregivers.

Please refer to the following website in HSA for details:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Safety_Information_and_Product_Recalls/Dear_Healthcare_Professional_Letters/2017/risk-of-severe-haemorrhagewithcotelliccobimetinib.html

In Hong Kong, Cotellic Tablets 20mg (HK-64797) is a pharmaceutical product registered by Roche Hong Kong Limited (Roche HK), and is a prescription only medicine. In January 2017, Roche HK had informed the Department of Health (DH) that the company issued a "Dear Healthcare Professional Letter" to local oncologists and pharmacists on the above risk, and the news was posted on the Drug Office website on 11 January 2017. So far, DH has not received any adverse drug reaction report related to the product. DH will remain vigilant on future safety update of the product by other overseas drug regulatory authorities.

Ends/Monday, April 24, 2017

Issued at HKT 15:00

As confirmed with Roche HK, the "Dear Healthcare Professional Letter" on additional cases of severe haemorrhage reported with Cotellic™ (cobimetinib) was issued to local oncologists and pharmacists on 11 January 2017.

Content last updated: Thursday, June 1, 2017