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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.)

12 Aug 2022

Dear Healthcare Professionals,

Nexavar (sorafenib): Assessing the potential risk of thrombotic microangiopathy

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of thrombotic microangiopathy (TMA) with the use of Nexavar. This safety review was triggered by a United States Food and Drug Administration update to the product safety information for Nexavar to include the risk of TMA, as well as international case reports published in the medical literature.

TMA is a group of rare, but serious and life-threatening conditions, involving the formation of clots in the small blood vessels. These clots can cause damage to organs and body systems by blocking proper blood flow. TMA is a medical emergency and requires rapid intervention. A number of factors, including congenital conditions (those present at birth), infection, cancer and drugs, can cause TMA.

Health Canada reviewed information provided by the manufacturer, and information resulting from searches of the Canada Vigilance database and the published literature. Health Canada reviewed 28 cases (1 Canadian, 27 international) of TMA in patients taking Nexavar. Of the 28 cases, 12 (all international) met the criteria for further assessment to determine if there was a link between the use of Nexavar and TMA. All 12 cases, including 6 published in the scientific literature, were found to be possibly linked to the use of Nexavar. Three deaths were reported (2 of which were assessed as having a possible link to Nexavar and 1 unlikely to be linked). There were no Canadian cases of TMA found to be linked to the use of Nexavar.

Health Canada's review of the available information concluded that there may be a link between the use of Nexavar and the risk of TMA. Health Canada will work with the manufacturer to update the Canadian product monograph for Nexavar to include the risk of TMA.

Please refer to the following website in Health Canada for details:
https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00286

In Hong Kong, there are 2 registered pharmaceutical products containing sorafenib. Both products are prescription-only medicines. So far, the Department of Health (DH) has received 18 cases of adverse drug reaction related to sorafenib, but these cases were not related to TMA. 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 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)