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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.)

28 Jun 2024

Dear Healthcare Professionals,

Nexavar (sorafenib): Assessing the potential risk of tumour lysis syndrome

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of tumour lysis syndrome (TLS) with the use of Nexavar. The safety review was triggered by a labelling update made by the European Medicines Agency and international case reports published in the medical literature.

TLS is a potentially life-threatening condition that can occur during cancer treatment. When cancer cells are killed by the cancer treatment, they release their contents (salts and proteins) into the blood. When cancer cells break down faster than the kidneys can remove these substances from the blood, it can cause changes to the chemical balance in the blood, which may result in damage to organs, most commonly the kidneys, heart and brain.

Health Canada reviewed information provided by the manufacturer, and from searches of the Canada Vigilance database, international databases and the scientific literature. At the time of the review, Health Canada had not received any Canadian reports of TLS in patients taking Nexavar.

Health Canada reviewed 9 international cases of TLS in patients taking sorafenib, including 8 from the published literature. All 9 cases were found to be possibly linked to the use of sorafenib, although a potential contribution from spontaneous TLS (cancer cell break down in the absence of treatment) could not be ruled out. The reported time to the onset of TLS ranged from 3 to 34 days after starting treatment with sorafenib. Five deaths were reported among the 9 cases assessed. All 5 deaths were found to be possibly linked to TLS from sorafenib treatment. However, other causes of death, such as cancer progression, could not be ruled out.

Health Canada reviewed 1 additional article published in the scientific literature. A link between sorafenib and TLS could not be established due to study limitations.

Health Canada's review found a possible link between the use of Nexavar and the risk of TLS. Health Canada is working with the manufacturer to update the Canadian product monograph for Nexavar to include the risk of TLS. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch Communication.

Please refer to the following website in Health Canada for details:
https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1715006032208

In Hong Kong, there are 5 registered pharmaceutical products containing sorafenib. All products are prescription-only medicines. So far, with regard to sorafenib, the Department of Health (DH) has received 20 cases of adverse drug reaction, but the cases were not related to TLS. 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 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,

(Terence MAN)
for Assistant Director (Drug)