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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.)

1 Mar 2024

Dear Healthcare Professionals,

Colistin (colistimethate sodium): Assessing the potential risk of pseudo-Bartter syndrome

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of pseudo-Bartter syndrome with the use of colistin (colistimethate sodium). The safety review was triggered by published cases of pseudo-Bartter syndrome with the use of colistin (colistimethate sodium) in the scientific literature.

Pseudo-Bartter syndrome is an acquired condition (not passed on from a parent) primarily presenting as metabolic alkalosis (an acid-base disorder), hypokalemia (low blood potassium) and other electrolyte abnormalities. Colistin (colistimethate sodium) is a prescription antibiotic drug authorized for sale in Canada to treat acute or chronic infections.

Health Canada reviewed the available information from searches of the Canada Vigilance database, international databases, and scientific literature. At the time of the review, Health Canada had not received any Canadian reports of pseudo-Bartter syndrome related to the use of colistin (colistimethate sodium). Health Canada reviewed 7 international cases of pseudo-Bartter syndrome in patients who were administered colistin (colistimethate sodium). All 7 cases were identified in the published literature. Of the 7 cases reviewed, 6 were found to be probably linked to the use of colistin (colistimethate sodium), and 1 was found to be possibly linked. In all 7 cases, hypokalemia, metabolic alkalosis, and loss of potassium in the urine were reported. Some cases also involved hypomagnesemia (low blood magnesium) and hypocalcemia (low blood calcium). In all 7 cases, electrolyte abnormalities resolved or significantly improved following the discontinuation of colistin (colistimethate sodium).

Health Canada's review of the available information found a link between the use of colistin (colistimethate sodium) and the risk of pseudo-Bartter syndrome. Health Canada is working with the

manufacturers to update the Canadian product monograph for colistin (colistimethate sodium)-containing products with a warning about reported cases of pseudo-Bartter syndrome.

Please refer to the following website in Health Canada for details:
https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1705515920269

In Hong Kong, there are 3 registered pharmaceutical products containing colistin (colistimethate sodium) for human use. All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to colistin (colistimethate sodium). 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)