衞生署藥物辦公室
藥物資訊及進出口管制科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND
IMPORT/EXPORT CONTROL DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

電話號碼 Tel. No.: (852) 3974 4175
詢問處 Enquiries (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:

(來函請敘明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

1 Nov 2024

Dear Healthcare Professionals,

Olanzapine: Assessing the potential risks of syndrome of inappropriate secretion of antidiuretic hormone and hyponatremia

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risks of syndrome of inappropriate secretion of antidiuretic hormone (SIADH) and hyponatremia with the use of olanzapine. The safety review was triggered by a safety report completed by a manufacturer of olanzapine-containing products on the risk of hyponatremia secondary to SIADH, which was prepared following the identification of a published case report during routine surveillance.

Olanzapine is a prescription drug authorized for sale in Canada for the treatment of schizophrenia and related psychotic disorders, and bipolar disorder. When administered intramuscularly, it may also be used for the rapid control of agitation in these patient populations.

Syndrome of inappropriate secretion of antidiuretic hormone is a condition in which the body makes too much antidiuretic hormone, a hormone that helps regulate the water balance in the body. Too much antidiuretic hormone causes more water to be held in the body and commonly leads to hyponatremia, which is low blood sodium levels.

Symptoms of hyponatremia include muscle cramps, tremor, headache, nausea, and vomiting. If blood sodium levels become too low or if sodium levels drop too quickly, symptoms may progress to seizures, coma and respiratory arrest (absence of breathing), with life-threatening or fatal consequences.

Health Canada reviewed the available information provided by manufacturers, and from searches of the Canada Vigilance database and the scientific literature. Health Canada reviewed 15 cases (1

Canadian and 14 international) of SIADH or hyponatremia in patients taking olanzapine. Twelve of those cases (1 Canadian) reported SIADH and 3 reported hyponatremia only. Of the 15 cases, 13 (11 SIADH [1 Canadian], 2 hyponatremia) were found to be possibly linked to the use of olanzapine and 2 (1 SIADH, 1 hyponatremia) could not be assessed due to missing or contradictory information. Overall, these cases provided limited evidence for a link between the use of olanzapine and the development of SIADH and hyponatremia due to the presence of confounders (other factors that may have contributed to the occurrence of SIADH or hyponatremia) and missing clinical information.

Health Canada also reviewed 30 articles published in the scientific literature that investigated or summarized existing evidence for the association between antipsychotics (including olanzapine) and the development of SIADH and hyponatremia. Due to study limitations, including the presence of confounders, there was limited evidence to support a link between the use of olanzapine and the development of SIADH and hyponatremia.

Health Canada's review could not confirm a definitive link between the use of olanzapine and the development of SIADH and hyponatremia. However, a possible link could not be ruled out.

While a definitive link could not be confirmed, Health Canada's review of the available information could not rule out a possible link between olanzapine and the risks of SIADH and hyponatremia. Despite the limited available evidence, the extensive use of olanzapine in Canada and vulnerability of the patient population who could be prescribed the drug warranted a precautionary approach for these risks. Health Canada will work with the manufacturers to update the CPM for all olanzapine-containing products to include the potential risks of SIADH and hyponatremia.

Please refer to the following website in Health Canada for details:
https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1725462803755

In Hong Kong, there are 44 registered pharmaceutical products containing olanzapine. All products are prescription-only medicines. So far, with regard to olanzapine, the Department of Health (DH) has received 25 cases of adverse drug reaction, but these cases were not related to SIADH and hyponatremia. 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,

p.p. (Terence MAN)
for Assistant Director (Drug)