

衛生署藥物辦公室
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

BY FAX

16 October 2013

(本函請註明此檔案號碼)

(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI

President

Hong Kong Academy of Medicine

(Fax Number: 2505 5577)

Dear Dr. LI,

Cinacalcet – New Warnings about the risk of QT prolongation and arrhythmia

Your attention is drawn to Health Canada's announcement with respect to the possible link between cinacalcet and abnormal heart rhythm associated with hypocalcemia. Stronger warnings had been added to the Canadian labelling information advising of this risk.

Cinacalcet is well known to cause hypocalcemia, which can cause QT prolongation and arrhythmia. Arrhythmia can be serious and, in some cases, may lead to sudden death. Health Canada had reviewed all available information and noted that QT prolongation and arrhythmia had been reported in a small number of patients with hypocalcemia treated with cinacalcet.

According to Health Canada, it is difficult to determine with certainty what role cinacalcet may have played in the development of QT prolongation or arrhythmia, as other risk factors were present at the same time. However, given the effect of hypocalcemia on the heart, the possibility of developing QT prolongation or arrhythmia with the use of cinacalcet could not be ruled out.

Health professionals are advised to monitor patients for signs of hypocalcemia, and prescribe cinacalcet with caution in patients with other risk factors for QT prolongation, such as known congenital long QT syndrome, or in patients who are taking other drugs known to cause QT prolongation. For patients treated with cinacalcet for chronic kidney disease and receiving dialysis, reduce dose or stop use if hypocalcemia, signs of QT prolongation, or arrhythmia continue. For these patients, cinacalcet should not be started if they have severe hypocalcemia.


Please refer to Health Canada's website for details:

<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/36267a-eng.php>

In Hong Kong, there are two registered pharmaceutical products containing cinacalcet, namely Regpara Tab 25mg (HK-58066) and 75mg (HK-58067). They are prescription-only medicines and indicated for the treatment of secondary hyperparathyroidism in patients undergoing maintenance dialysis. So far, the Department of Health has not received any adverse drug reaction report in relation to the drug. In view of Health Canada's latest recommendations, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,


(Ms. Pamela LI)

for Assistant Director (Drug)

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*