衞生署藥物辦公室
藥物資訊及警戒科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

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

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

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

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Dear Healthcare Professionals,

Dopamine agonists: Assessing the potential risk of dopamine agonist withdrawal syndrome

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of dopamine agonist withdrawal syndrome (DAWS) with the use of the dopamine agonists apomorphine, bromocriptine, cabergoline, pergolide, pramipexole, quinagolide, ropinirole and rotigotine following a manufacturer-initiated Canadian Product Monograph (CPM) update to include DAWS under the Warnings and Precautions section for Mirapex (pramipexole). DAWS may occur after reducing the dose of or stopping some dopamine agonists, and includes symptoms such as apathy, anxiety, depression, fatigue, sweating, panic attacks, insomnia, irritability and pain.

Health Canada reviewed information from Canadian and international databases of reported adverse reactions, as well as from the scientific literature. Health Canada reviewed 23 case reports (2 Canadian and 21 international) of DAWS in patients treated with dopamine agonists. The 21 international cases included 5 cases reported to the Canada Vigilance database, and 16 that were only available through the scientific literature. Three cases of DAWS were found to be probably linked to the use of pramipexole, 5 cases were possibly linked, and 2 cases (1 Canadian) could not be further assessed due to insufficient information. One case was found to be probably linked with the use of quinagolide. Five cases were found to be possibly linked with the use of ropirinole, and 2 cases could not be further assessed due to insufficient information. One case of DAWS was found to be possibly linked to the use of bromocriptine and pramipexole taken together. Two cases, 1 with cabergolide and pergolide taken together and the other with pramipexole and ropirinole taken together, could not be further assessed due to lack of information. In 2 cases (1 Canadian), patients were taking pramipexole, ropinirole and rotigotine separately at different times. For these cases, a probable link was found with the use of pramipexole and a possible link was found with the use of ropirinole. The use of rotigotine and the risk of DAWS could not be further assessed due to missing information.

Health Canada's review of the available information has established a link between the use of pramipexole, quinagolide or ropinirole and the risk of DAWS. The CPM for pramipexole has been updated to include a warning on the risk of DAWS. Health Canada will work with the manufacturers of quinagolide and ropinirole to update their CPMs to also include a warning about this safety issue.

At this time, there is not enough information to establish a link between apomorphine, bromocriptine, cabergoline, pergolide or rotigotine and DAWS. As a precaution, Health Canada will work with the manufacturers of these products to include the potential risk of DAWS in their CPMs to raise awareness among healthcare professionals that DAWS has been observed for other members of the dopamine agonist drug class, and encourage reporting of this potential safety issue.

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=SSR00269

In Hong Kong, there are registered pharmaceutical products containing apomorphine (3 products), bromocriptine (5 products), cabergoline (1 product), pramipexole (13 products), quinagolide (3 products), ropinirole (12 products) and rotigotine (4 products). All products are prescription-only medicines. There is no registered pharmaceutical product containing pergolide. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to the above dopamine agonists. In light of the above Health Canada's announcement, the matter will be discussed by 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 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,

(Joseph LEE)
for Assistant Director (Drug)