

衛生署藥物辦公室
藥物註冊及進出口管制部

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Risperidone - Restriction of the dementia indication

Your attention is drawn to the Health Canada's announcement regarding the restriction of risperidone's indication to severe dementia of the Alzheimer type.

Health Canada's decision to limit risperidone's indication to severe dementia of the Alzheimer type is based on a comprehensive evaluation of the safety information related to all antipsychotic drugs which indicated a higher risk of cerebrovascular adverse events in patients with the mixed or vascular dementia compared to those with dementia of the Alzheimer type. The indication for risperidone in dementia has been updated and restricted to the short-term symptomatic management of aggression or psychotic symptoms in patients with severe dementia of the Alzheimer type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. The indication no longer includes the treatment of other types of dementia such as vascular and mixed types of dementia. This updates affect all oral risperidone products.

Physicians are advised to assess the risks and benefits of the use of risperidone in elderly patients with severe dementia of the Alzheimer type, taking into account risk predictors for stroke or existing cardiovascular comorbidities in the individual patients.

Please refer to the Health Canada's website for details:

<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/43797a-eng.php>

In Hong Kong, there are 77 registered pharmaceutical products containing risperidone, including Risperdal oral products registered by Johnson & Johnson (Hong Kong) Ltd. All of them are prescription-only medicines. Some of the products are indicated for use in dementia. So far, the Department of Health has not received any relevant adverse drug reaction report related to risperidone. In view of the Health Canada's announcement, 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 report any adverse events caused by 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 digest of drug safety news and information issued by Drug Office.

Yours faithfully,


(Grant NG)
for Assistant Director (Drug)

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