

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,

Gabapentin (Neurontin): risk of severe respiratory depression

Your attention is drawn to the announcement by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) regarding the risk of severe respiratory depression for gabapentin. A European review of gabapentin was triggered by reports of patients developing respiratory depression without concomitant use of opioids. This reaction has already been recognised with concomitant use of gabapentin with opioids. Having considered the available evidence from worldwide spontaneous reports and in the literature, the review recommended that the product information for gabapentin should be amended to include warnings for severe respiratory depression (frequency rare; may affect up to 1 in 1,000 patients post-marketing).

The patient leaflet that accompanies gabapentin is being updated to include warnings about breathing problems, which if severe may need emergency and intensive care. The leaflet advises patients to seek medical help if they experience any trouble breathing or are taking shallow breaths.

Please be aware that when prescribing gabapentin in patients who require concomitant treatment with opioid medicines, patients should be carefully observed for signs of central nervous system (CNS) depression, such as somnolence, sedation, and respiratory depression, and the dose of either gabapentin or the opioid should be reduced appropriately.

In UK, there have been 50 Yellow Card reports of respiratory depression or dyspnoea associated with gabapentin between 19 February 1996 and 1 September 2017. Of these cases, 17 report opioids as co-suspect or concomitant medications.

MHRA advises healthcare professionals on the following:

- aware of the risk of CNS depression, including severe respiratory depression, with gabapentin.
- consider whether dose adjustments might be necessary in patients at higher risk of respiratory depression, including elderly people, patients with compromised respiratory function, respiratory or neurological disease, or renal impairment, and patients taking other CNS depressants.

Please refer to the MHRA's website for details:

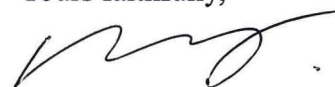
<https://www.gov.uk/drug-safety-update/gabapentin-neurontin-risk-of-severe-respiratory-depression>

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aspire to be an internationally renowned public health authority*

In Hong Kong, there are 24 registered pharmaceutical products containing gabapentin and they are all prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction (ADR) related to gabapentin. In view of the above MHRA'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 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,



(Paul WONG)

for Assistant Director (Drug)