

衛生署藥物辦公室
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



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

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.:

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

10 Feb 2023

Dear Healthcare Professionals,

Rocuronium: Assessing the potential risk of mydriasis

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of mydriasis with the use of rocuronium. The safety review was triggered by international case reports published in the literature concerning this risk.

Mydriasis is a condition in which the pupil is not responsive to external light stimulation and remains large (dilated) for a prolonged period. Rocuronium is a prescription drug that belongs to a group of drugs referred to as muscle relaxants. Rocuronium is authorized for sale in Canada to relax muscles during an operation as part of the general anesthesia and to facilitate mechanical ventilation in patients requiring intensive care.

Health Canada reviewed information provided by manufacturers, from foreign regulatory agencies, and from searches of the Canada Vigilance database and published literature. At the time of the review, Health Canada had not received any Canadian reports of mydriasis related to the use of rocuronium. Health Canada reviewed 9 international cases of mydriasis in patients administered rocuronium. Of the 9 cases assessed, 3 were found to be probably linked to the use of rocuronium, 2 were found to be possibly linked, 1 was unlikely to be linked and 3 could not be assessed.

Three cases (2 probable and 1 possible) involved adult patients with serious infection requiring mechanical ventilation. All 3 cases resolved following discontinuation of rocuronium. Two cases (1 probable and 1 possible) involved newborn infants undergoing surgery. One newborn infant experiencing prolonged general muscle relaxation received medication to reverse the mydriasis. The remaining case resolved following discontinuation of rocuronium.

Health Canada's review of the available information found a link between the use of rocuronium and

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

the risk of mydriasis in mechanically ventilated adult patients with systemic infection, and in newborn infants undergoing surgery. Mydriasis is expected to reverse when rocuronium is discontinued. Health Canada will work with the manufacturers to update the Canadian product monograph for rocuronium-containing products to include the risk of mydriasis.

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=SSR00292>

In Hong Kong, there are 7 registered pharmaceutical products containing rocuronium. All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to rocuronium. 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 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,



(Terence MAN)

for Assistant Director (Drug)