

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,

**Isotretinoin (Roaccutane): rare reports of erectile dysfunction and decreased libido**

Your attention is drawn to the announcement by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) that a routine European Union review showed that some patients taking isotretinoin had reported sexual dysfunction adverse effects, including erectile dysfunction and decreased libido. One possible mechanism for this effect may be through a reduction in plasma testosterone levels. The review recommended that sexual dysfunction including erectile dysfunction and decreased libido should be added to the list of side effects in the product information. The package leaflet for patients will include “Problems getting or maintaining an erection and lower libido” as possible side effects.

In UK, MHRA has received 14 Yellow Card reports of sexual dysfunction associated isotretinoin between the beginning of 1985 and 7 September 2017. In the same time period, there have been 49 reports of erectile or ejaculation dysfunction, and 23 reports of decreased or loss of libido associated with isotretinoin. MHRA estimates that over the past few years, around 30,000 patients (male and female) per year have been treated with isotretinoin.

MHRA also reminds that rare reports of depression, exacerbated depression, anxiety, aggressive tendencies, mood alterations, and psychotic symptoms in association with isotretinoin treatment. Very rarely, suicidal ideation, suicide attempts, and death by suicide have been reported. Particular care should be taken in patients with a history of depression. Monitor all patients for signs of depression and refer for appropriate treatment if necessary. Further psychiatric or psychological evaluation may be necessary after discontinuation of treatment with isotretinoin.

MHRA advises healthcare professionals on the following:

- aware of reports of sexual side effects, including erectile dysfunction and decreased libido, in patients taking oral isotretinoin, indicated for severe acne.
- the exact incidence of these adverse reactions is unknown but considering the number of patients in UK taking the medicine, reports are understood to be rare.

Please refer to the MHRA's website for details:

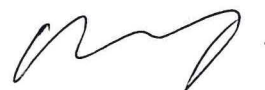
<https://www.gov.uk/drug-safety-update/isotretinoin-roaccutane-rare-reports-of-erectile-dysfunction-and-decreased-libido>

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aspire to be an internationally renowned public health authority*

In Hong Kong, there are 11 registered pharmaceutical products containing isotretinoin and they are all prescription-only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reactions (ADR) related to isotretinoin, but these cases were not related to sexual dysfunction, including erectile dysfunction and decreased libido, or mood disorders. 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](mailto: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)