

衛生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓

2319 8458

電話號碼 Tel. No.:

詢問處 Enquiries (852) 2319 8458

傳真號碼 Faxline No. (852) 2803 4962

本署檔號 OUR REF.: DH DO PRIE/7-30/15

(來函請註明此檔案號碼)

(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,



DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

25 May 2017

Finasteride: rare reports of depression and suicidal thoughts

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency's (MHRA) announcement regarding the MHRA has received reports of depression and, in rare cases, suicidal thoughts in men taking finasteride 1 mg (Propecia) for male pattern hair loss. The public should be aware that depression is also associated with finasteride 5 mg (Proscar).

Finasteride is a 5 α -reductase-type-2 inhibitor. In the 1 mg dose (Propecia), it is indicated for the treatment of male pattern hair loss (androgenetic alopecia). In the 5 mg dose (Proscar), it is indicated for the treatment and control of benign prostatic hyperplasia.

Some men have reported episodes of depressive illness in association with the use of Propecia for male pattern hair loss. Some men also reported having suicidal thoughts.

Depression and suicidal thoughts have been reported in men with and without a previous history of depression. Depressed mood has been previously recognised with Propecia. A recent review of the evidence has suggested more significant depression can occur and so the advice is being updated to reflect this.

The product information for Proscar already lists depression as a possible adverse reaction and is being updated in light of a recent review.

The MHRA advised healthcare professionals of the following:

- since finasteride has been marketed there have been a number of spontaneous adverse drug reaction reports suggesting a possible link to depression, and in rare cases, suicidal thoughts
- advise patients to stop finasteride 1 mg (Propecia) immediately if they develop depression and inform a healthcare professional
- be aware that the product information for finasteride 5 mg (Proscar) already lists depression as a possible adverse reaction

Healthcare professionals are reminded that adverse reactions related to sexual function have been reported in association with finasteride. These include decreased libido, erectile dysfunction, and ejaculation disorders (such as decreased volume of ejaculate).

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/finasteride-rare-reports-of-depression-and-suicidal-thoughts>

In Hong Kong, there are 35 registered pharmaceutical products containing finasteride, including 1mg tablets (13 products) and 5mg tablets (22 products), and they are prescription only medicines. Related news regarding changes to the professional labels for finasteride 1 mg and 5 mg to expand the list of sexual adverse events reported to US FDA as some of these events have been reported to continue after the drug is no longer being used was issued by US FDA and was posted on the Drug Office website on 13 April 2012. The Department of Health (DH) had issued letters to inform local healthcare professionals on the risk on 13 April 2012. The matter has been discussed by the Registration Committee of the Pharmacy and Poisons Board on 17 February 2015 and concluded that sales pack labels and/or package inserts to be updated with the new safety warnings by US FDA. So far, the DH has received one case of adverse drug reaction in connection with finasteride products which is not related to depression, suicidal thoughts or sexual dysfunction. In view of the significant depression with suicidal thought with finasteride reported in the above MHRA 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,



(Joseph LEE)

for Assistant Director (Drug)