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MSD

DHPC

04 Oct 2018

Direct Healthcare Professional Communication (DHPC)

Possible risks of sexual dysfunction and psychiatric disorders with medicinal products containing finasteride (1 mg and 5mg dosage) and recommendations for informing patients

Dear Healthcare Professional,

The Marketing Authorization Holders of the Propecia (containing finasteride 1 mg) with the indication "androgenetic alopecia" and Proscar (finasteride 5 mg) with the indication "benign prostatic hyperplasia", in agreement with the Saudi Food & Drug Authority (SFDA), inform you about the below safety aspects.

Summary
After the launch of medicinal products containing finasteride, side effects such as sexual dysfunction as well as psychiatric disorders have been reported. In order to support you in the benefit-risk assessment in making a therapeutic decision especially for the treatment of androgenetic alopecia (1 mg dosage), we would like to draw your attention to the following safety concerns:

- Patients should be aware of the risk of experiencing the adverse event (AE) of sexual dysfunction (including erectile dysfunction, ejaculation disorder, and decreased libido) during finasteride therapy. Patients should also be informed that case reports have been received of sexual dysfunction AEs that persisted after discontinuation of therapy.

- Healthcare Professionals should carefully monitor patients during treatment with finasteride for psychiatric symptoms (including anxiety, depression and suicidal ideation). If a patient treated with 1 mg finasteride develops psychiatric symptoms, treatment should be stopped and the patient advised to seek medical advice. If a patient treated with 5 mg finasteride develops psychiatric symptoms, the patient should be advised to seek medical advice.

- Further information can be found in the respective prescribing information.

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Further information on medicinal products containing finasteride

Finasteride is an active substance in the group of 5-alpha-reductase inhibitors. The 5 mg dosage for the treatment of benign prostatic hyperplasiahas been approved since 1993, and the 1 mg dosage for the treatment of androgenetic alopecia since 2005 in Saudi Arabia. Medicinal products containing finasteride, like all medicinal products, are subject to continuous safety monitoring by pharmaceutical companies and the regulatory authorities, which includes the reporting of side effects and the risk profile of the medicinal product. As a result of this ongoing monitoring, we are sending this DHPC letter to minimize potential risks for patients.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC):

SFDA call center: 19999
Toll free phone: 8002490000
E-mail: npc.drug@sfda.gov.sa
Website: http://ade.sfda.gov.sa/
Fax: +966-11-2057662

Pharmacovigilance department in MSD:

Telephone: +966112506719
Fax: +966114006484
Email: saudi.pharmacovigilance@merck.com

Yours sincerely,

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