Editor's note: This English translation was done by a third party. The original report can be accessed here.

Korea Food and Drug Administration
Drug Safety Information
June 2012 (p. 723)

- Safety Information Subject: Finasteride (Oral) (Finasteride)
- Classification number: [02590] Other genitourinary and anal drugs
- Information Classification: Overseas Safety Information
- Source of Information: Food and Drug Administration (FDA)
- Information: According to "Several side effects related to sexual function persist after discontinuation of medication"

Revision of permitted matters and cautionary recommendations
Processing result: Distribution of safety letter

(Drug Safety Information Team No.-1047, 2012. 4.16.)

Action Details

Issue date: April 16, 2012

Related products

- Product name: 65 companies, 87 items including "Proscar Tablet" of MSD Korea (see attached)

- Formulation name: Formulation containing "finasteride" ingredient

- Indications: Treatment of benign prostatic hyperplasia (5 mg formulation), androgenetic alopecia (androgen) in adult males (ages 18-41) alopecia treatment (1 mg formulation)

Main contents

- US FDA: "Some sexual side effects persist after discontinuation of medication"

- Information phase: Complete evaluation

- Finasteride recently used by the US Food and Drug Administration (FDA) to treat benign prostatic hyperplasia

- Administration of a formulation containing 5 mg and a formulation containing 1 mg of finasteride used to treat androgenetic alopecia

- The permission is revised in relation to some sexual side effects that persist even after discontinuation. Caution health care professionals and patients.

- This from the US FDA Adverse Event Reporting System (AERS) and safety database of companies holding product approvals.

As a result of reviewing post-marketing cases reported in 1 mg formulation: decreased libido, ejaculation disorder, orgasm disorder, etc. persist even after discontinuation of treatment.

Such cases were reported, but a clear causal relationship between formulations containing finasteride and sexual side effects has not been established. Therefore, doctors and pharmacists should pay attention to the contents and provide guidance on prescription, administration and medication.

We ask that you do so, and our agency will review the overall safety and effectiveness of the medication as soon as possible. We inform you that we plan to take necessary measures, such as change of permission, through this evaluation.

For reference, 65 companies and 87 items including MSD Korea's "Proscar Tablet" are licensed in Korea.

The following adverse reactions were reported in post-marketing use:

- Reproductive system and breast: ejaculation disorder, breast tenderness and hypertrophy, testicular pain.

- Erectile dysfunction, male infertility and/or decreased semen quality that persists after discontinuation of finasteride use. Normalization or improvement of semen quality has been reported after discontinuation.

Lastly, if you have any questions about the case or have any doubts related to the item, or if you are aware of a case, please contact:

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Thank you.

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