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Reaksi

DRUG SAFETY NEWS

NATIONAL CENTRE FOR ADVERSE DRUG REACTION MONITORING, NPCB

Mission: This publication provides information and recommendations to healthcare professionals to enhance communication of drug safety updates, raise awareness of adverse drug reactions reported, and stimulate additional adverse drug reaction reporting. It is a newsletter published bimonthly by the National Centre for Adverse Drug Reaction Monitoring, National Pharmaceutical Control Bureau (NPCB), Malaysia.

TO REPORT AN ADVERSE DRUG REACTION

Online

1. Visit www.bpfk.gov.my
2. Click on MADRAC (Adverse Drug Reaction)
3. Click on Reporting Online
4. Submit the form once completed.

Mail

1. Fill up the Adverse Drug Reaction form
2. Mail it to :
   National Centre for Adverse Drug Reaction Monitoring,
   Centre for Post Registration of Products, National Pharmaceutical Control Bureau, Ministry of Health,
   PO Box 319, Jalan Sultan,
   46730,Petaling Jaya,
   Selangor

Telephone
03-78835400

Fax
03-79567151

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Finasteride: Sexual Dysfunction that Continued After Treatment Discontinuation

In May 2012, the Marketing Authorization Holder, MSD (M) Sdn Bhd had proposed to update their package inserts of both Proscar® (finasteride 5mg) and Propecia® (finasteride 1mg) to expand the list of sexual adverse events as some of the events had been reported to last after drug discontinuation. The proposal followed the United States Food and Drug Administration (US FDA) mandated labeling changes in April 2012. Both Proscar® and Propecia® labels were revised to include decreased libido that continued after discontinuation of the drug. Information on male infertility and/or poor semen quality that normalised or improved after drug discontinuation was also included.

Proscar® is approved for the treatment and control of benign prostatic hyperplasia (BPH) and for the prevention of urologic events to reduce the risk of acute urinary retention as well as to reduce the risk of surgery including transurethral resection of the prostate (TURP) and prostatectomy. At a lower strength of 1mg, Propecia® is approved for the treatment of men with male pattern hair loss (androgenetic alopecia) to increase hair growth and prevent further hair loss.

In Malaysia:
There are 6 finasteride-containing products registered in Malaysia. Since year 2000, the National Centre for ADR Monitoring has received 43 reports related to finasteride, of which 7 reports (16.3%) were related to sexual dysfunction, including ejaculation failure, premature ejaculation, impotence, decreased libido, erectile dysfunction and semen abnormality. Of these, 4 reported the outcomes as not recovered at the time of reporting, whereas 2 with unknown outcome and 1 recovered.

Advice for healthcare providers:

- Finasteride remains a safe and effective drug for its approved indications. A clear cause and relationship between finasteride and the sexual adverse events that continued after drug discontinuation has not been established.
- Inform and counsel patient on the potential adverse events patient might experience with the use of finasteride.
- Any adverse events suspected to be associated with the use of finasteride should be reported to the National Centre for ADR Monitoring, National Pharmaceutical Control Bureau.

Suspected ADRs reported on Finasteride and Sexual Dysfunction: 2 case reports

In March 2012, a 52-year-old patient was prescribed Propecia® for the indication of male pattern hair loss. After 7 days, he experienced libido and erectile dysfunction. Due to the event, the patient stopped treatment with Propecia® after consulting his doctor. After 2 weeks following treatment discontinuation, the condition did not improve. However, in May 2012, the patient reported the outcome has gradually recovered.

Similarly in another report, a 63-year-old patient was started on Proscar® for prostate enlargement in February 2007. A few weeks later, the patient experienced ejaculation failure but he continued taking the medication. Subsequently in July 2007, the patient stopped taking the medication before consulting his doctor a week later. The outcome was reported as not yet recovered at the time of reporting. Concomitant medications include metformin and losartan / hydrochlorothiazide.

Finasteride: Potential Rare Risk of Breast Cancer in Men

On April 16, 2012, the Drug Control Authority had issued a directive to update the package insert for all finasteride-containing products to add safety information on rare reports of breast cancer in men. Male breast cancer has been reported in a small number of patients worldwide with both the 1mg and 5mg formulations of finasteride, as published in the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) public assessment report. Until November 2009, 50 cases of male breast cancer have been reported worldwide with 5mg finasteride (Proscar®) and 3 cases with the 1mg finasteride (Propecia®). Most cases reported with Proscar® use occurred within 5 years of starting treatment. However, the overall incidence of male breast cancer in clinical trials in patients who received 5 mg finasteride was not significantly different compared to patients who did not receive finasteride. A possible mechanism for this association relates to the pharmacodynamics of finasteride. Finasteride use leads to the decrease in dihydrotestosterone (DHT) level which is accompanied by increases in testosterone and oestradiol levels. The increase in sex steroid levels has the potential to increase the risk of breast cancer.

In Malaysia:
Presently, there are 6 registered products containing finasteride. Overall, 43 reports have been received by the National Centre for ADR Monitoring, but none has been associated with male breast cancer.

Advice for healthcare providers:

- Counsel patient to promptly report any changes in their breast tissue such as lumps, pain, gynaecomastia or nipple discharge.
- Any adverse events suspected to be associated with the use of finasteride should be reported to the National Centre for ADR Monitoring, National Pharmaceutical Control Bureau.