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National Center of Pharmacovigilance
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To: Health Professionals

MEDICATION SAFETY NOTE

SAFETY REVIEW OF FINASTERIDE AND THE POTENTIAL RISK OF SERIOUS MUSCLE-RELATED SIDE EFFECTS

THE DEPARTMENT OF PHARMACOVIGILANCE OF THE MINISTRY OF HEALTH, MONITORING THE ALERTS AND INFORMATIVE NOTES ISSUED BY INTERNATIONAL REGULATORY AUTHORITIES REGARDING MEDICINES, CONSIDERS PERTINENT TO COMMUNICATE THE FOLLOWING INFORMATION:

Medicines regulatory agency Health Canada analyzed the risk of possible serious muscle-related side effects with the use of finasteride. The safety review focused on the potential risks of serious muscle-related adverse events such as rhabdomyolysis (muscle pain with breakdown of muscle tissue and an increase in certain muscle proteins known as creatine kinase [CK] enzymes), myopathy of muscles with pain and an increase in the enzyme CK, and muscle disorders such as pain, weakness, atrophy (wasting) or stiffness.

Security Review Results

• At the time of the review, Health Canada had received 11 reports of serious muscle-related side effects suspected to be related to the use of finasteride. Of these, 4 cases were evaluated:

✓ A patient experienced myopathy while being treated for hair loss.

✓ A patient with benign prostatic hyperplasia reported muscle pain (myalgia).

✓ Two patients experienced muscle weakness; one was using finasteride to treat hair loss, but the indication is unknown for the fourth case.

• Three of these patients recovered after discontinuation of finasteride (outcome unknown in the fourth case). In the remaining 7 reports, there was not enough information to establish a link between finasteride and muscle-related side effects.

• Three additional cases of serious muscle-related side effects were reported in the literature with the use of finasteride. One reported case of myalgia was excluded from the review because other known factors

may have caused the condition. The remaining 2 cases reported myalgias with increased muscle enzymes, or rhabdomyolysis after the use of finasteride to treat hair loss in men. These patients recovered after discontinuation of finasteride.

Conclusion and actions

• Health Canada's review of the available information concluded that the risk of serious muscle-related side effects with the use of finasteride could not be ruled out.

• Currently, finasteride product information does not include the potential risk of serious muscle-related side effects. Health Canada has recommended that manufacturers update product information for finasteride-containing products to address this potential risk.

• Health Canada will continue to monitor safety information involving finasteride-containing products to identify potential harm.

Situation in Panama

To date, commercial products containing the active ingredient finasteride are registered in the National Directorate of Pharmacy and Drugs. Currently, the National Center for Pharmacovigilance has not received notifications of suspected adverse reactions related to muscle after the use of products containing finasteride as the active ingredient. We recommend health professionals to take into consideration the communicated safety information and to provide pharmacotherapeutic follow-up to patients under treatment with finasteride.

Patients are advised to consult their healthcare professional with any questions or concerns about their therapy.

Actions of the National Pharmacovigilance Center

The National Pharmacovigilance Center has published the following drug safety note related to the use of finasteride: Note 0859/CNFV/DNFD of July 17, 2014, entitled “Cases of adverse reactions associated with the inappropriate use of products containing the active ingredients finasteride, spironolactone and minoxidil in combination with retinoids for the treatment of alopecia in women,” it can be found on the website of the Ministry of Health in the section “Drug Safety Notes.” (http://www.minsa.gob.pa./informacion-salud/alertas-ycomunicados).

Given the suspicion of adverse reactions, pharmaceutical failures and therapeutic failure, we recommend health professionals to notify the CNFV of the Ministry of Health (MINSA). Phone 512-9404; e-mail: fvigilancia@minsa.gob.pa.

We ask you to extend this information to health professionals. Health professionals are encouraged to take into consideration the information set forth in this safety note.

Bibliographical sources:

• Agencia Reguladora de Medicamentos Health Canada
https://www.canada.ca/en/health-canada/services/druqs-health-products/medeffect-canada/safety-reviews/summary-safety-review-finasteride-assessing-potential-risk-serious-muscle-related-side-effects.html

• Base de Datos de Registro Sanitario de la Direccion Nacional de Farmacia y Drogas; Ministerio de Salud, Panama. [Consultada: 07/08/17]