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

Chinese National Medical Products Administration

Drug Safety Warning
Pharmacovigilance Alert No. 4
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Canada warns of potential risk of suicidal ideation with finasteride

On February 26, 2019, Health Canada issued information warning of a possible association between finasteride (brand names Proscar, Propecia) and the risk of suicidal ideation. Prolipizide (5mg oral tablet) and Promethazine (1mg oral tablet) are prescription drugs in Canada, which are used for the treatment of benign prostatic hyperplasia (BPH) and male hair loss respectively. They were approved for marketing in 1992 and 1998. Generic versions of finasteride are also available.

Based on individual Canadian and international reported cases, Health Canada initiated an assessment of the risk of suicidal ideation and/or suicidal behavior associated with finasteride use and conducted a series of assessments to investigate finasteride use and suicidal ideation/possible correlation between self-harm.

Health Canada has been monitoring this safety issue since 2011. The first safety assessment was completed in 2012 and reassessment within 2 years is recommended. The second assessment was completed in 2014, but the information available at that time did not determine whether finasteride use was associated with suicide/self-harm. As a precautionary measure, clinicians were informed of this potential risk and reassessment after the next 2 years was recommended. Canada initiated this assessment based on the above recommendations and reported known cases.

At the time of this review, Health Canada had received 26 adverse event reports of suicide or self-harm related to finasteride use in Canada. Between 2012 and 2016, the reported rate of finasteride-related suicide/self-harm incidents in Canada increased 2.5-fold. The assessments reported in Canada could neither confirm nor deny a causal association, so an association of finasteride with suicide/self-harm-related events was considered likely.

A search of the World Health Organization (WHO) Adverse Drug Reaction Database identified 368 international reports of suicide/self-harm incidents reported in patients using finasteride as of September 16, 2018. Health Canada also evaluated five studies of finasteride and suicide-related events published between 2015 and 2018 that supported an association between finasteride and risk of suicidal ideation.

In 2018, the European Medicines Agency (EMA) added a warning to the product inserts for Proscar and Propecia, warning of reports of suicidal ideation in patients taking finasteride (1mg and 5mg strengths).

Patients on this drug should be monitored for psychiatric symptoms. Currently, the U.S. Food and Drug Administration (FDA) has not required changes to the labeling of Proscar or Propecia. Health Canada assessed that international reports, literature and regulatory agency information neither confirm nor deny a causal link between finasteride and suicide/self-harm. This review concluded that there may be an association between finasteride and the risk of suicidal ideation.

Health Canada has notified manufacturers to update the Canadian product label to add a warning about this potential safety issue.

(Health Canada website)