Canada: Summary Safety Review - Finasteride and Dutasteride - Assessing the Potential Risk of Sexual Dysfunction

Product
Finasteride-containing products and dutasteride-containing products

Potential Safety Issue
Sexual dysfunction

Key Messages

- The risk of sexual dysfunction with the use of finasteride and dutasteride is known. Health Canada reviewed this risk to identify and assess newly emerging safety information, and to determine whether current risk minimization measures remain appropriate.
- Health Canada's review, which builds on the evidence that existed at the time of market authorization for finasteride and dutasteride, provides a larger body of evidence on the link between the use of these products and the risk of sexual dysfunction.
- Health Canada will work with the manufacturers to enhance the existing product safety information in the Canadian product monograph (CPM) for all finasteride-containing products and dutasteride-containing products to also include a warning about the risk of sexual dysfunction. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Overview
The risk of sexual dysfunction with the use of finasteride and dutasteride is known and labelled in the CPM for all finasteride-containing products and dutasteride-containing products. However, following media attention, Health Canada reviewed this risk to identify and assess newly emerging safety information, and to determine whether current risk minimization measures remain appropriate.

Use in Canada

- Finasteride is a prescription drug authorized for sale in Canada for the treatment and control of prostate gland enlargement (benign prostatic hyperplasia), and for the treatment of male pattern hair loss (androgenic alopecia).
- Finasteride has been marketed in Canada since 1992 under the brand name Proscar (5 mg tablets), and since 1998 under the brand name Propecia (1 mg tablets). Generic versions are also available.
- Dutasteride is a prescription drug authorized for sale in Canada for the treatment of benign prostatic hyperplasia.
- Dutasteride has been marketed in Canada since 2003 under the brand name Avodart (0.5 mg oral capsules) and since 2011 under the brand name Jalyn (0.5 mg dutasteride/0.4 mg tamsulosin oral capsules). Generic versions are also available.

Safety Review Findings

- Health Canada reviewed the available information from searches of the Canada Vigilance Database and the scientific literature.
- Health Canada reviewed 18 Canadian cases of sexual dysfunction in patients taking finasteride (17 cases) or dutasteride (1 case). Of the 18 cases, 17 (16 finasteride and 1 dutasteride) were found to be possibly linked to their use, while the remaining case, which was in a patient taking finasteride, was unassessable due to limited clinical information.
- Health Canada also reviewed articles published in the scientific literature, which, overall, provided a growing body of evidence supporting the link between the use of finasteride and dutasteride, and the risk of sexual dysfunction.

Conclusions and Actions

- Health Canada's review, which builds on the evidence that existed at the time of market authorization for finasteride and dutasteride, provides a larger body of evidence on the link between the use of these products and the risk of sexual dysfunction.
- Health Canada will work with the manufacturers to enhance the existing product safety information in the CPM for all finasteride-containing products and dutasteride-containing products to also include a warning about the risk of sexual dysfunction.
- Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.
- Health Canada will continue to monitor safety information involving finasteride and dutasteride, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.

Please refer to the following website in Health Canada for details:
https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1778504746731

In Hong Kong, there are 32 and 11 registered pharmaceutical products containing finasteride and dutasteride respectively. All products are prescription-only medicines. So far, the Department of Health (DH) has received 5 cases of adverse drug reaction with regard to finasteride, of which 2 cases were reported as decreased libido and erectile dysfunction. With regard to dutasteride, the DH has received 4 cases of adverse drug reaction, but these cases were not related to problems with sexual function.

Related news on problems with sexual function associated with the use of finasteride and dutasteride was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 25 May 2017, with the latest update posted on 12 May 2026. Letters to inform local healthcare professionals were issued by the DH on 25 May 2017 and 9 May 2025. In Feb 2015, the Registration Committee of the Pharmacy and Poisons Board discussed the matter and decided that the sales pack label and/or package insert of finasteride-containing

products should include safety information on problems with sexual function (including decreased libido and erectile dysfunction). As previously reported on 9 May 2025 and 12 May 2026, the matter will be further discussed by the Registration Committee of the Pharmacy and Poisons Board.

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