



The FDA Safety Information and Adverse Event Reporting Program

5-alpha reductase inhibitors (5-ARIs): Label Change –

Increased Risk of Prostate Cancer

Drugs in the 5-ARI class include finasteride and dutasteride. These drugs are marketed under the brand-names Proscar, Propecia, Avodart, and Jalyn

[Posted 06/09/2011]

FDA 修訂了 5- α 還原酶抑制劑的仿單警語：使用 5- α 還原酶抑制劑會增加前列腺癌的風險。新的警示訊息是根據自兩大隨機對照試驗。

在使用 5- α 還原酶抑制劑之前，需先進行評估，排除泌尿系統不適用 5- α 還原酶抑制劑的狀況，例如前列腺癌。

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AUDIENCE: Urology, Family Medicine, Internal Medicine

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FDA notified healthcare professionals that the Warnings and Precautions section of the labels for the 5-alpha reductase inhibitor (5-ARI) class of drugs has been revised to include new safety information about the increased risk of being diagnosed with a more serious form of prostate cancer (high-grade prostate cancer).

The new safety information is based on FDA's review of two large, randomized controlled trials—the Prostate Cancer Prevention Trial (PCPT) and the Reduction by Dutasteride of Prostate Cancer Events (REDUCE) trial. Proscar, Avodart, and Jalyn are approved to improve symptoms of an enlarged prostate gland (benign prostatic hyperplasia or BPH). Proscar and Avodart are also approved to reduce the risk of urinary retention or surgery related to an enlarged prostate. Propecia is approved to treat male pattern hair loss.

Prior to initiating therapy with 5-ARIs, perform appropriate evaluation to rule out other urological conditions, including prostate cancer, that might mimic benign prostatic hyperplasia (BPH).