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Translated by  
Pharmaceuticals and Medical Devices Agency



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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of PRECAUTIONS

## Finasteride

August 29, 2023

### **Therapeutic category**

Other hormone preparations (including antihormone preparations)

### **Non-proprietary name**

Finasteride

### **Safety measure**

PRECAUTIONS should be revised.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director-General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Careful Administration (N/A)	Careful Administration <u>Patients with depression, depressed state, or a history of those diseases or patients with a history of suicidal ideation or a suicide attempt [Suicidal ideation, suicide attempt, and completed suicide have been reported, although the causal relationship with this drug is unclear.]</u>
Important Precautions (N/A)	Important Precautions <u>Suicidal ideation, suicide attempt, and completed suicide have been reported, although the causal relationship with this drug is unclear. Patients should be carefully monitored. In addition, if suicidal ideation or a suicide attempt is observed, patients should be instructed to discontinue taking this drug and contact a physician immediately.</u>

Note: Designated as a drug requiring preparation of a Drug Guide for Patients

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
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<p>8. IMPORTANT PRECAUTIONS</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Suicidal ideation, suicide attempt, and completed suicide have been reported, although the causal relationship with this drug is unclear. Patients should be carefully monitored. In addition, if suicidal ideation or a suicide attempt is observed, patients should be instructed to discontinue taking this drug and contact a physician immediately.</u></p>
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>(N/A)</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p><u>9.1 Patients with Complication or History of Diseases, etc.</u></p> <p><u>Patients with depression, depressed state, or a history of those diseases or patients with a history of suicidal ideation or a suicide attempt</u></p> <p><u>Suicidal ideation, suicide attempt, and completed suicide have been reported, although the causal relationship with this drug is unclear.</u></p>

Note: Designated as a drug requiring preparation of a Drug Guide for Patients

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