

*Editor's note: This English translation was done by a third party. The original report can be accessed [here](#).*

## **Austrian Federal Office for Safety in Health Care**

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Our code: PHV-10060266-A-170608  
PHV Issue: Finasteride

Dear Ladies and Gentlemen:

Based on a PSUR Single Assessment (PSUSA) by the Committee for Pharmacovigilance Risk Assessment (PRAC), the outcome of which was approved by the CMDh has been confirmed, there will be a change in the permits for the marketing of medicinal products containing the active substance finasteride.

To be included in the relevant sections of the finasteride 5 mg product information. Changes (new text is **underlined and bold**, deleted text is ~~striketrough~~).

### **Summary of Product Characteristics**

- Section 4.4

The following warning should be added:

#### **Mood changes and depression**

**In patients treated with finasteride 5 mg, mood changes including depressed mood, depression and, more rarely, suicidal thoughts have been reported. Patients suffering psychiatric symptoms should be monitored. If such symptoms appear, the patient should be advised to seek medical advice.**

#### **Leaflet**

Section 2

Warnings and Precautions

#### **Mood changes and depression**

**In patients treated with <drug name>, mood changes such as depressed mood, depression and, less commonly, reported suicidal thoughts. If you notice any of these symptoms, consult your doctor immediately.**

To be included in the relevant sections of the finasteride 1 mg product information Changes (new text is **underlined and bold**, deleted text is ~~strikethrough~~).

### **Summary of Product Characteristics**

- Section 4.4

The following warning should be added:

#### **Mood changes and depression**

**In patients treated with finasteride 1 mg, mood changes including depressed mood, depression and, more rarely, suicidal thoughts reported. Patients suffering from psychiatric symptoms should be monitored. If such symptoms appear, finasteride should be discontinued and the patient advised to seek medical advice.**

- Section 4.8

The side effect “~~depressed mood~~” should be replaced by “depression” under the system organ class

### **Leaflet**

Section 2

Warnings and Precautions

#### **Mood changes and depression**

**In patients treated with <drug name>, mood changes such as depressed mood, depression and, less commonly, reported suicidal thoughts. If you notice any of these symptoms, stop taking <medicine name> and contact your doctor immediately for advice.**

Section 4

The side effect “~~depressed mood~~” should be replaced by “depression” with frequency occasionally replaced.