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

Classification No: 250, Drug for other reproductive organs and anal conditions Classification No: 267, Agent for hair (epilation, hair loss, hair color and hair nurturing)

Directive for Revised Approval (Safety Data Processing) (Pharmaceutical Safety Assessment) Division- No. .)] . .

Finasteride Single-Drug (Tablet) (Finasteride)

Precaution

Warning

Mood swings including depressed mood, depression and suicidal thoughts were reported by patients treated with 1 mg of finasteride. Please make sure to observe patients for psychological symptoms. If any of the above symptoms are found in a patient, stop the treatment with finasteride and consult to a medical provider.

Item	Previous Approval	Revision
1. Warning	(Omitted) <newly added=""></newly>	(Same as the previous approval) New) Mood swing and depression Mood swings including depressed mood, depression and suicidal thoughts were reported by patients treated with 1 mg of finasteride. Please make sure to observe patients for psychological symptoms. If any of the above symptoms are found in a patient, stop the treatment with finasteride and consult to a medical provider.

Revised Approval for Finasteride Single-Drug (Tablet) 14 - 1---Duesdarie