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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 Dutasteride

October 20, 2015

### **Non-proprietary name**

Dutasteride

### **Safety measure**

Precautions should be revised in the package insert.

The Clinically significant adverse reaction subsection should be newly added in the Adverse reaction section and in the new Clinically significant adverse reaction subsection, the following text should be added (underlined parts are revised):

Hepatic function disorder, jaundice:

Hepatic function disorder or jaundice associated with increased levels of AST (GOT), ALT (GPT), bilirubin, etc. may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.