



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 Abiraterone acetate

July 7, 2015

Non-proprietary name

Abiraterone acetate

Safety measure

Precautions should be revised in the package insert.

Information on hepatic function disorder in the Important precautions section should be revised as follows (underlined parts are revised):

Fulminant hepatitis may occur. In addition, hepatic function disorder associated with increased levels of ALT (GPT), AST (GPT), or bilirubin, etc. may occur and may result in hepatic failure. Patients should be carefully monitored through periodic liver function tests during administration of the drug (particularly, hepatic function tests should be conducted frequently during the initial treatment stage).

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following text should be revised (underlined parts are revised):

Fulminant hepatitis, hepatic failure, and hepatic function disorder:

Fulminant hepatitis may occur. In addition, hepatic function disorder associated with increased levels of AST (GOT), ALT (GPT), or bilirubin, etc. may occur and may result in hepatic failure. Patients should be carefully monitored through periodic liver function tests during administration of the drug. If any abnormalities are observed, appropriate measures such as dose reduction, cessation of the drug, or discontinuation of administration should be adopted.

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