Revision of PRECAUTIONS

enzalutamide

October 21, 2014

Non-proprietary Name
enzalutamide

Safety measure
Precautions should be revised in the package insert.

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

Thrombocytopenia:
Thrombocytopenia may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.