



# Summary of investigation results

## Abiraterone acetate

July 7, 2015

### **Non-proprietary name**

Abiraterone acetate

### **Brand name (Marketing authorization holder)**

Zytiga Tablets 250 mg (Janssen Pharmaceutical K.K.)

### **Indications**

Castration-resistant prostate cancer

### **Summary of revision**

1. Alerts on fulminant hepatitis and hepatic failure should be added to the hepatic function disorder subsection in the Important precautions section.
2. 'Fulminant hepatitis and hepatic failure' should be added to the hepatic function disorder subsection in the Clinically significant adverse reactions section.

### **Background of the revision and investigation results**

Cases associated with fulminant hepatitis or hepatic failure have been reported in patients treated with abiraterone acetate in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.



*This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

### **The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

A total of 9 cases associated with fulminant hepatitis or hepatic failure have been reported (including 5 cases for which a causal relationship to the product could not be ruled out). Of the 9 cases, 5 fatal cases have been reported (including a case for which a causal relationship to the product could not be ruled out).