



Summary of investigation results

Abiraterone acetate

February 2, 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

- ‘Patients with hypokalaemia or risks of hypokalaemia due to factors of complications or concomitant drugs’ should be added in the Careful administration section.
- An alert on hypokalaemia should be added in the Important precautions.
- The following should be added in the Clinically significant adverse reactions section:
 - Hypokalaemia
 - Thrombocytopenia
 - Rhabdomyolysis

Background of the revision and investigation results

● Hypokalaemia

Cases of hypokalaemia have been reported in patients treated with abiraterone acetate in Japan. There were a fatal case of arrhythmia due to hypokalaemia and cases of serious symptomatic hypokalaemia. Some patients had hypokalaemia before the treatment with abiraterone acetate and other patients had risks of hypokalaemia due to factors of complications or concomitant drugs. Thus, following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

● Thrombocytopenia

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



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- Rhabdomyolysis

Cases of rhabdomyolysis have been reported in patients treated with abiraterone acetate in foreign countries, and the company core data sheet (CCDS)* has been updated. Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

- Hypokalaemia

A total of 6 cases of adverse events suggestive of hypokalaemia have been reported. Although there were 4 cases in which causality could not be ruled out, in 1 case the use of a concomitant drug did not comply with the recommended dosage and administration as stated in the package insert of abiraterone acetate. A fatality has been reported. Although causality could not be ruled out in the fatal case, the use of a concomitant drug did not comply with the recommended dosage and administration as stated in the package insert of abiraterone acetate.

- Thrombocytopenia

A total of 11 cases of adverse events suggestive of thrombocytopenia have been reported (including 4 cases in which causality could not be ruled out).

- Rhabdomyolysis

No case of adverse events suggestive of rhabdomyolysis has been reported.

*NOTE

The CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

Pharmaceuticals and Medical Devices Agency

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