



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.

Revision of Precautions

Abiraterone acetate

February 2, 2015

Non-proprietary Name

abiraterone acetate

Safety measure

Precautions should be revised in the package insert.

In the Careful administration section, the following texts should be added (underlined parts are revised):

'Patients with hypokalaemia or risks of hypokalaemia due to factors of complications or concomitant drugs'

Information on increased blood pressure, hypokalaemia, and fluid retention in the Important precautions section should be revised as follows (underlined parts are revised):

Increased blood pressure, hypokalaemia, and/or fluid retention may occur. Cautions should be paid to the following:

- (1) Serum electrolyte levels such as serum potassium should be measured before the start of treatment with this drug. If hypokalaemia is observed, serum potassium level should be corrected before starting therapy.
- (2) Patients should be carefully monitored through periodic blood pressure measurements, blood tests, body weight measurement, etc. during treatment with this drug. Appropriate measures including treatment with an antihypertensive or supplementation of potassium as necessary should be taken.

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

Hypokalaemia:

Hypokalaemia with symptoms including convulsion and muscular weakness may occur, and arrhythmia has been reported in some cases. Patients should be monitored through periodic measurements of serum electrolyte levels such as serum potassium. If any abnormalities are

Published by
Ministry of Health, Labour and Welfare



Translated by
Pharmaceuticals and Medical Devices Agency



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.

observed, appropriate measures such as supplementation of potassium and cessation of this drug should be taken.

Thrombocytopenia:

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

Rhabdomyolysis:

Rhabdomyolysis may occur. Attention should be paid to muscular weakness, myalgia, increased creatine kinase (creatine phosphokinase), and increased blood and urine myoglobin. If these symptoms are observed, administration of this drug should be discontinued and appropriate measures should be taken.

Pharmaceuticals and Medical Devices Agency

Office of Safety I

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan

E-mail: safety.info@pmda.go.jp