



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

cabazitaxel acetate

December 22, 2014

Non-proprietary Name

cabazitaxel acetate

Safety measure

Precautions should be revised in the package insert.

Information on bone marrow depression in Important precautions section should be revised as follows:

Serious bone marrow depression may frequently occur. Caution should be exercised for the following points (A higher incidence of bone marrow depression such as neutropenia and febrile neutropenia has been reported especially in patients whose body surface area is small or elderly patients.):

- a. When cabazitaxel acetate is administered, proper use of granulocyte-colony stimulating factor (G-CSF) should be considered by referring to the current guidelines or recommendations. Primary prophylaxis with G-CSF product should be considered especially in patients with risk factors for febrile neutropenia (ex. ≥ 65 years old, poor performance status, medical history of febrile neutropenia, potent pretreatment history such as extended radiation exposure, and bone marrow tumor cell infiltration)
- b. Patients should be carefully monitored by frequent laboratory tests (ex. blood tests) after administration of cabazitaxel acetate. If any abnormalities are observed, appropriate measures such as drug suspension, dose reduction, and/or discontinuation of administration should be taken. (See Precautions of dosage and administration section)
- c. Careful attention should be paid especially to infection. Signs and symptoms such as decreased neutrophil counts, increased levels of C-reactive protein, and pyrexia should be monitored. If infection occurred or was aggravated, appropriate measures such as administration of antibiotics should be taken immediately. If neutropenia occurred, the current guidelines or recommendations should be referred for proper use of antibiotics.

NOTE: Information on proper use of cabazitaxel acetate should be immediately provided to healthcare professionals.

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