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.

Summary of investigation results

Zoledronic acid hydrate

November 22, 2016

Non-proprietary name

Zoledronic acid hydrate

Brand name (Marketing authorization holder)

(1) Zometa for I.V. Infusion 4 mg/5 mL, 4 mg/100 mL (Novartis Pharma K.K.), and the others

(2) Reclast for I.V. Infusion 5 mg (Asahi Kasei Pharma Corporation)

Indications

(1) 1. Hypercalcemia of malignancy

2. Bone lesion associated with multiple myeloma or bone metastases from solid tumors

(2) Osteoporosis

Summary of revision

"Fanconi syndrome" should be added to the "acute renal failure, interstitial nephritis" subsection in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of Fanconi syndrome have been reported in patients treated with zoledronic acid hydrate in Japan, and the company core datasheet (CCDS*) for zometa has been revised. 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.

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

(1) A total of 11 cases associated with Fanconi syndrome have been reported (including 7 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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(2) No cases associated with Fanconi syndrome have been reported.

NOTE:

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