



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 Zoledronic acid hydrate

November 22, 2106

Non-proprietary name

Zoledronic acid hydrate

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section regarding acute renal failure, interstitial nephritis, the following text should be revised (underlined parts are revised):

Acute renal failure, interstitial nephritis, Fanconi syndrome:

Renal disorders such as acute renal failure, interstitial nephritis, and Fanconi syndrome (Proximal kidney tubule injury may cause hypophosphataemia, hypokalaemia, metabolic acidosis etc.) may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as the discontinuation of administration should be adopted.