



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

Bisphosphonates

Alendronate Sodium Hydrate, Ibandronate Sodium Hydrate, Etidronate Disodium, Zoledronic Acid Hydrate, Pamidronate Disodium Hydrate, Minodronic Acid Hydrate, Risedronate Sodium Hydrate,

May 31, 2016

Non-proprietary name

- a. Alendronate sodium hydrate
- b. Ibandronate sodium hydrate
- c. Etidronate disodium
- d. Zoledronic acid hydrate
- e. Pamidronate disodium hydrate
- f. Minodronic acid hydrate
- g. Risedronate sodium hydrate

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

Cases of osteonecrosis of external auditory canal have been reported in patients treated with bisphosphonates. In several cases, osteonecrosis of external canal occurred in association with ear infection and trauma. Healthcare professionals should advise patients to consult an otolaryngologist if symptoms such as otitis externa, otorrhoea, and ear pain persist.



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

Osteonecrosis of external auditory canal:

Osteonecrosis of external auditory canal may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.