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*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 (preparations indicated for osteoporosis)

January 17, 2023

### **Therapeutic category**

Agents affecting metabolism, n.e.c. (not elsewhere classified)

### **Non-proprietary name**

Zoledronic acid hydrate

### **Safety measure**

Precautions should be revised.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.2 Patients with renal impairment</p> <p>Patients with severe renal impairment (creatinine clearance less than 35 mL/min)</p> <p>This drug should not be administered. Acute kidney injury may occur.</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.2 Patients with renal impairment</p> <p>Patients with severe renal impairment (creatinine clearance less than 35 mL/min)</p> <p><u>(1) This drug should not be administered. Acute kidney injury may occur.</u></p> <p><u>(2) In an epidemiological study conducted in Japan using a medical information database, among patients with renal impairment who used bisphosphonates for the treatment of osteoporosis, particularly in those with severe renal impairment (eGFR less than 30 mL/min/1.73 m<sup>2</sup>), an increased risk of hypocalcaemia (corrected serum calcium level less than 8 mg/dL) has been reported compared with those with normal renal function.</u></p>

[Reference] Summary of MID-NET® study (Database study using MID-NET® on risk assessment of hypocalcaemia in patients with renal impairment receiving bisphosphonates):

<https://www.pmda.go.jp/files/000249791.pdf>

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