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Translated by
Pharmaceuticals and Medical Devices Agency



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

Minodronic acid hydrate

January 17, 2023

Therapeutic category

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

Non-proprietary name

Minodronic acid hydrate

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p>Careful Administration</p> <p>Patients with serious renal disorder [Excretion may be delayed.]</p>	<p>Careful Administration</p> <p>Patients with serious renal disorder [Excretion may be delayed. <u>In addition, 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 m²), 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>

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 serious renal disorder</p> <p>Excretion may be delayed.</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.2 Patients with renal impairment</p> <p>Patients with serious renal disorder</p> <p><u>(1)</u> Excretion may be delayed.</p>

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	<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 m²), 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>
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