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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Alendronate sodium hydrate

January 17, 2023

Therapeutic category

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

Non-proprietary name

Alendronate sodium 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
Careful Administration Patients with serious renal impairment [Safety has not been established due to the small number of cases in which this drug has been administered.]	Careful Administration Patients with serious renal impairment [Safety has not been established due to the small number of cases in which this drug has been administered. 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 m^2), an increased risk of hypocalcaemia (corrected serum calcium level less than 8 mg/dL) has been reported compared with those with normal renal function.]

[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
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with renal impairment	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with renal impairment

Patients with serious renal impairment Clinical trials have not been conducted in patients with serious renal impairment.	Patients with serious renal impairment (1) Clinical trials have not been conducted in patients with serious renal impairment. (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^2), an increased risk of hypocalcaemia (corrected serum calcium level less than 8 mg/dL) has been reported compared with those with normal renal function.

[Reference] Summary of MID-NET® study (Database study on risk assessment of hypocalcaemia in patients with renal impairment receiving bisphosphonates using MID-NET®):
https://www.pmda.go.jp/files/000249791.pdf