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Revision of Precautions

Etidronate disodium

January 17, 2023

Therapeutic category

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

Non-proprietary name

Etidronate disodium

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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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
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with renal impairment Patients with serious renal disorder This drug should not be administered. Excretion may be inhibited.	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with renal impairment Patients with serious renal disorder (1) This drug should not be administered. Excretion may be inhibited. (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 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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