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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Roxadustat

November 16, 2022

Therapeutic category

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

Non-proprietary name

Roxadustat

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
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS Central hypothyroidism may occur during administration of this drug. Cases in which central hypothyroidism developed approximately 2 weeks after initiation of administration have been reported. Patients should be carefully monitored through methods including periodical thyroid function tests (measurement of thyroid-stimulating hormone (TSH), free T3, free T4) during treatment with this drug.
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Central hypothyroidism Central hypothyroidism, in which the blood TSH level is within the normal range or low, may occur. If symptoms or signs appear, appropriate measures should be taken such as discontinuation of this drug and administration of thyroid hormone preparations as necessary.

N/A: Not Applicable. No corresponding language is included in the current Precautions.

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