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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

Relugolix

September 8, 2020

Therapeutic category

Other hormone preparations (including antihormone preparations)

Non-proprietary name

Relugolix

Safety measure

Precautions should be revised in the package insert.

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>(N/A)</p> <p>Important Precaution</p> <p>(N/A)</p>	<p><u>Careful Administration</u></p> <p><u>Patients with submucosal fibroid</u></p> <p>Important Precautions</p> <p><u>When administering this drug to patients with submucosal fibroid, severe abnormal uterine bleeding may occur. Patients should be carefully monitored and if any abnormalities are observed, appropriate measures should be taken. Patients should be instructed to immediately contact medical institutions if they experience heavy bleeding at one time.</u></p>

N/A: Not Applicable, because the section is not included in the current package insert.

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