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Revision of Precautions

Fulvestrant

May 19, 2020

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Fulvestrant

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Injection site necrosis, ulcer:</u> <u>Injection site necrosis, ulcer may occur. Patients should be carefully monitored and if any abnormalities are observed, appropriate measures should be taken.</u>

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

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