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Translated by
Pharmaceuticals and Medical Devices Agency



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

Osimertinib mesilate

December 3, 2019

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Osimertinib mesilate

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, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1. Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1. Clinically Significant Adverse Reactions <u>Congestive cardiac failure and decreased left ventricular ejection fraction</u>

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

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