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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

September 24, 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, 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>Adverse Reactions Clinically Significant Adverse Reactions N/A</p>	<p>Adverse Reactions Clinically Significant Adverse Reactions <u>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme:</u> <u>Toxic epidermal necrolysis, oculomucocutaneous syndrome, and erythema multiforme may occur. Patients should be carefully monitored and appropriate measures should be taken such as discontinuing this drug if any abnormalities are observed.</u></p>

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
<p>11. ADVERSE REACTIONS Adverse reactions listed below may occur. Patients should be carefully monitored and appropriate measures should be taken if any abnormalities are observed such as discontinuing this drug. 11.1. Clinically Significant Adverse Reactions (N/A)</p>	<p>11. ADVERSE REACTIONS Adverse reactions listed below may occur. Patients should be carefully monitored and appropriate measures should be taken if any abnormalities are observed such as discontinuing this drug. 11.1. Clinically Significant Adverse Reactions <u>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme</u></p>

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

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