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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Olmesartan medoxomil

Olmesartan medoxomil/azelnidipine

January 21, 2020

Therapeutic category

Antihypertensives

Non-proprietary name

Olmesartan medoxomil,

Olmesartan medoxomil/azelnidipine

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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Interstitial pneumonia:</u> <u>Interstitial pneumonia accompanied by pyrexia, cough, dyspnoea, or abnormal chest X-ray may occur. In such cases, administration of this drug should be discontinued and appropriate measures should be taken such as administration of corticosteroids.</u>

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>Interstitial pneumonia</u> <u>Interstitial pneumonia accompanied by pyrexia, cough, dyspnoea, or abnormal chest X-ray may occur. In such cases, administration of this drug should be discontinued and appropriate measures should be taken such as administration of corticosteroids.</u>

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

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