



Summary of Investigation Results

Preparations containing olmesartan medoxomil

January 21, 2020

Non-proprietary name

- a. Olmesartan medoxomil
- b. Olmesartan medoxomil/azelnidipine

Branded name (Marketing authorization holder)

- a. Olmetec OD Tablets 5 mg, 10 mg, 20 mg, 40 mg (Daiichi Sankyo Co., Ltd.), and the others
- b. Rezaltas Combination Tablets LD, HD (Daiichi Sankyo Co., Ltd.)

Indications

Hypertension

Summary of revisions

“Interstitial pneumonia” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of interstitial pneumonia have been reported in patients treated with olmesartan medoxomil in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.



Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

Cases involving interstitial pneumonia

- a. A total of 6 cases have been reported to date (including 2 cases for which a causal relationship between the drug and event could not be ruled out). No patient mortalities have been reported to date.
- b. 1 case has been reported to date (A causal relationship between the drug and event could not be established for this case.) No patient mortalities have been reported to date.