



Summary of investigation results

Azilsartan

April 23, 2015

Non-proprietary name

azilsartan

Brand name (Marketing authorization holder)

Azilva Tablets 10 mg, 20 mg, and 40 mg (Takeda Pharmaceutical Co., Ltd)

Indications

Hypertension

Summary of revision

'Hepatic function disorder' should be added to the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of hepatic function disorder have been reported in patients treated with azilsartan in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 13 cases associated with hepatic function disorder has been reported (including 5 cases in which causality could not be ruled out). Of the 13 cases, no fatality has been reported.