This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Products Containing Azilsartan

January 12, 2016

Non-proprietary name

a. Azilsartan

b. Azilsartan/Amlodipine Besilate

Brand name (Marketing authorization holder)

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

b. Zacras Combination Tablets LD and HD (Takeda Pharmaceutical Co., Ltd.)

Indications

Hypertension

Summary of revision

“Rhabdomyolysis” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of rhabdomyolysis have been reported in patients treated with azilsartan and azilsartan/amlodipine besilate 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. A total of 5 cases associated with rhabdomyolysis have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

b. A case associated with rhabdomyolysis has been reported (the causal relationship to the product could not be ruled out). No fatality has been reported.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp