Published by Ministry of Health, Labour and Welfare



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

Azilsartan

April 23, 2015

Non-proprietary name

azilsartan

Safety measure

Precautions in the package insert should be revised.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following texts should be added (underlined parts are added):

Hepatic function disorder:

Hepatic function disorder associated with elevated AST (GOT), ALT (GPT), and γ-GTP levels may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.