



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/Amlodipine Besilate, Amlodipine Besilate

January 12, 2016

Non-proprietary name

Azilsartan/Amlodipine Besilate

Amlodipine Besilate

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection regarding hepatic function disorder and jaundice of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Fulminant hepatitis, hepatic function disorder, and jaundice:

Fulminant hepatitis, hepatic function disorder associated with increased levels of AST (GOT), ALT (GPT), γ -GTP, etc. or jaundice may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be adopted.

In the Clinically significant adverse reaction subsection regarding thrombocytopenia of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Agranulocytosis, leukopenia, and thrombocytopenia:

Agranulocytosis, leukopenia, or thrombocytopenia may occur. Patients should be carefully monitored through clinical laboratory testing, etc. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be adopted.



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.

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

Rhabdomyolysis:

Rhabdomyolysis may occur. Patients should be carefully monitored. If symptoms including myalgia, feelings of weakness, increased creatinine kinase (creatinine phosphokinase), or increased blood and urine myoglobin are observed, administration of this drug should be discontinued and appropriate measures should be adopted. In addition, caution should be exercised for development of acute kidney injury due to rhabdomyolysis.

NOTE

- Amlodipine besilate is designated as a drug requiring preparation of a Drug Guide for Patients.