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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Aliskiren Fumarate/Amlodipine Besilate

January 12, 2016

Non-proprietary name

Aliskiren Fumarate/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, 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 and leukopenia 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.

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

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Rhabdomyolysis:

Rhabdomyolysis may occur. Patients should be carefully monitored. If symptoms including myalgia, feelings of weakness, increased creatinine kinase (creatine 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.

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