



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

Telmisartan and Telmisartan/Amlodipine besilate

June 3, 2014

Non-proprietary Name

- Telmisartan
- Telmisartan/Amlodipine besilate

Safety measure

Precautions section should be revised in the package inserts.

In Precautions for concomitant use subsection of Interactions section, information on angiotensin-converting enzyme inhibitors (ACEIs) should be revised to include the following texts (underlined parts are revised):

ACEIs

Clinical symptoms and measures:

Renal impairment (including acute renal failure), hyperkalaemia, and/or hypotension may occur.

Patients should be carefully monitored for renal function, serum potassium level, and blood pressure.

Mechanism and risk factors:

Concomitant use with ACEIs may increase an effect of renin-angiotensin system blockade.