



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, Azilsartan/Amlodipine besilate, Irbesartan, Irbesartan/Amlodipine besilate, Olmesartan medoxomil, Olmesartan medoxomil/Azelnidipine, Candesartan cilexetil, Valsartan, Valsartan/Amlodipine besilate, and Valsartan/Cilnidipine

June 3, 2014

### **Non-proprietary Name**

- Azilsartan
- Azilsartan/Amlodipine besilate
- Irbesartan
- Irbesartan/Amlodipine besilate
- Olmesartan medoxomil
- Olmesartan medoxomil/Azelnidipine
- Candesartan cilexetil
- Valsartan
- Valsartan/Amlodipine besilate
- Valsartan/Cilnidipine

#### Safety measure

Precautions section should be revised in the package inserts.

In Precautions for concomitant use subsection of Interactions section, the following texts should be added (underlined parts are revised):

#### Angiotensin-converting enzyme inhibitors (ACEIs)

Clinical symptoms and measures:

Renal impairment, 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.