Revision of PRECAUTIONS
Candesartan cilexetil/Amlodipine besilate, Candesartan cilexetil/Hydrochlorothiazide,
Valsartan/Hydrochlorothiazide, and Losartan potassium/Hydrochlorothiazide

June 3, 2014

Non-proprietary Name
- Candesartan cilexetil/Amlodipine besilate
- Candesartan cilexetil/Hydrochlorothiazide
- Valsartan/Hydrochlorothiazide
- Losartan potassium/Hydrochlorothiazide

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.

In Other drugs that have an antihypertensive effect paragraph of Precautions for concomitant use
subsection, ‘ACEIs’ should be deleted.