Revision of PRECAUTIONS

Telmisartan/Hydrochlorothiazide

June 3, 2014

Non-proprietary Name
Telmisartan/Hydrochlorothiazide

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.

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