Revision of PRECAUTIONS
Irbesartan/Trichlormethiazide

June 3, 2014

Non-proprietary Name
Irbesartan/Trichlormethiazide

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 antihypertensives* paragraph of Precautions for concomitant use subsection, ‘ACEIs’ should be deleted.