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Revision of PRECAUTIONS

Losartan potassium

June 3, 2014

Non-proprietary Name

Losartan potassium

Safety measure

Precautions section should be revised in the package inserts.

In Important Precautions section, information on increased serum potassium and creatinine levels should be revised to include the following texts (underlined parts are revised):

> Increased serum potassium and creatinine levels are likely to occur in patients with diabetic nephropathy in type 2 diabetes mellitus. Patients should be carefully monitored through periodic monitoring (every 2 weeks in an early phase of the treatment and approximately once monthly in a subsequent stable phase) for serum potassium and creatinine levels during administration of this drug. If any abnormalities are observed in serum potassium and/or creatinine levels, appropriate measures should be taken. Careful attention should be paid especially to the concomitant use with angiotensin-converting enzyme inhibitors (ACEIs) because increased risks of acute renal failure and/or hyperkalaemia have been reported in concomitant use of this drug and ACEIs.

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

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.

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