



## Summary of investigation results

### Losartan potassium

June 3, 2014

#### **Non-proprietary Name**

Losartan potassium

#### **Brand Name (Marketing Authorization Holder)**

NU-LOTAN tablets 25 mg, 50 mg, 100 mg (MSD K.K.) and the others

#### **Indications**

- Hypertension
- Diabetic nephropathy in type 2 diabetes mellitus concurrently with hypertension and proteinuria

#### **Summary of revision**

The following information should be added in Important Precautions section:

Increased risks of acute renal failure and/or hyperkalaemia have been reported in concomitant use with angiotensin-converting enzyme inhibitors (ACEIs). Attention should be paid to the concomitant use of this drug and ACEIs.

#### **Background of the revision and investigation results**

A Randomized controlled double-blind trial was conducted to evaluate the efficacy and safety of the concomitant use of ACEIs and angiotensin II receptor blockers in patients with diabetic nephropathy in type 2 diabetes mellitus. A literature on the trial reported that risks of acute renal failure and hyperkalaemia were significantly higher in the group of concomitant use of losartan and lisinopril than in the group of losartan monotherapy. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package inserts was necessary.