



## Summary of investigation results

### Tolvaptan

Aug 6, 2014

#### Non-proprietary Name

Tolvaptan

#### Brand Name (Marketing Authorization Holder)

- a. Samsca tablets 7.5 mg (Otsuka Pharmaceutical Co., Ltd.)
- b. Samsca tablets 15 mg (Otsuka Pharmaceutical Co., Ltd.)
- c. Samsca tablets 30 mg (Otsuka Pharmaceutical Co., Ltd.)

#### Indications

- a. Samsca tablets 7.5 mg
  - Fluid retention in patients with cardiac failure, which is not adequately responsive to other diuretics such as loop diuretics
  - Fluid retention in patients with hepatic cirrhosis, which is not adequately responsive to other diuretics such as loop diuretics
  - Control of disease progression in patients with autosomal dominant polycystic kidney who already had increased kidney volume and whose kidney volume was further rapidly increasing
- b. Samsca tablets 15 mg
  - Fluid retention in patients with cardiac failure, which is not adequately responsive to other diuretics such as loop diuretics
  - Control of disease progression in patients with autosomal dominant polycystic kidney who already had increased kidney volume and whose kidney volume was further rapidly increasing
- c. Samsca tablets 30 mg
  - Control of disease progression in patients with autosomal dominant polycystic kidney who already had increased kidney volume and whose kidney volume was further rapidly increasing



### **Summary of revision**

‘Pancytopenia’ and ‘thrombocytopenia’ should be added in Clinically significant adverse reactions section.

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

Cases of pancytopenia or thrombocytopenia have been reported in patients treated with tolvaptan in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

### **The number of reported adverse reaction and fatal cases in the last 3 fiscal years**

A total of 5 cases of pancytopenia has been reported (including 3 cases in which causality could not be ruled out). Of the 5 cases, no fatality has been reported.

A total of 9 cases of thrombocytopenia have been reported (including 3 cases in which causality could not be ruled out). Of the 9 cases, no fatality has been reported.