

This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

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

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Pharmaceuticals and Medical Devices Agency

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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.

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