



Summary of investigation results

Tolvaptan

March 20, 2018

Non-proprietary name

Tolvaptan

Brand name (Marketing authorization holder)

Samsca tablets 7.5 mg, 15 mg, 30 mg, Samsca granules 1 % (Otsuka Pharmaceutical Co., Ltd.)

Indications

Samsca tablets 7.5 mg, Samsca granules 1 %

- Treatment of fluid retention in heart failure when treatment with other diuretics including loop diuretics is not sufficiently effective.
- Treatment of fluid retention in hepatic cirrhosis when treatment with other diuretics including loop diuretics is not sufficiently effective.
- Slowing the progression of autosomal dominant polycystic kidney disease in patients with an increased kidney volume and a rapid rate of kidney volume increase.

Samsca tablets 15 mg

- Treatment of fluid retention in heart failure when treatment with other diuretics including loop diuretics is not sufficiently effective.
- Slowing the progression of autosomal dominant polycystic kidney disease in patients with an increased kidney volume and a rapid rate of kidney volume increase.

Samsca tablets 30 mg

- Slowing the progression of autosomal dominant polycystic kidney disease in patients with an increased kidney volume and a rapid rate of kidney volume increase.



Summary of revision

“Acute hepatic failure” should be added to the portion of the Clinically Significant Adverse Reactions section concerning hepatic impairment

Investigation results and background of the revision

Cases of acute hepatic failure have been reported in patients treated with tolvaptan in Japan. Based on the results of their investigation of the evidence currently available and in consultation with expert advisors, MHLW/PMDA concluded that revision of the package insert was necessary.

Number of adverse reactions and patient mortalities reported in the previous 3 fiscal years in Japan

A total of 11 cases associated with acute hepatic failure have been reported to date (including 4 cases for which a causal relationship with the product could not be ruled out.). 7 of these 11 cases were fatal (including 3 cases for which a causal relationship with the product could not be ruled out).