

June 17, 2022

**Otsuka Pharmaceutical Factory launches a vasopressin V<sub>2</sub>-receptor antagonist “Tolvaptan OD tablets 7.5 mg Otsuka”**

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shinichi Ogasawara; “OPF”) announces that “Tolvaptan OD tablets 7.5 mg Otsuka” (nonproprietary name: tolvaptan), a vasopressin V<sub>2</sub>-receptor antagonist, has been listed in the National Health Insurance (NHI) drug price list and launched today. Tolvaptan received regulatory approval on February 15, 2022.


Tolvaptan is an authorized generic drug with the same drug substance and additives manufactured using the same methods in the same factory as “Samsca<sup>®</sup> OD tablets 7.5 mg,” which is a new dosage form of the vasopressin V<sub>2</sub>-receptor antagonist “Samsca<sup>®</sup>.” Samsca was discovered and developed by our group company Otsuka Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan; President and Representative Director: Makoto Inoue) and launched in December 2010.

Tolvaptan is a therapeutic agent that selectively blocks the binding of vasopressin to the V<sub>2</sub>-receptors in the collecting duct of the kidney, thereby increasing the excretion of free water and reducing the re-absorption of water from urine into the blood without directly affecting the excretion of sodium and other electrolytes. Tolvaptan was launched for the treatment of excess water retention in patients with hepatic cirrhosis when the treatment with other diuretics including loop diuretics is ineffective.

OPF, as a leading IV solution company, has an extensive network from acute care hospitals to home health care through regular visits to various clinical departments. We will continue to contribute to patients and healthcare professionals by providing products and detailed information.

Based on the corporate philosophy of “Otsuka-people creating new products for better health worldwide,” the Otsuka Group is dedicated to contributing to the health of people around the world.

## Product Information

Brand name	Tolvaptan OD tablets 7.5 mg Otsuka
Generic name	Tolvaptan
Indications	Treatment of excess water retention in patients with hepatic cirrhosis when the treatment with other diuretics including loop diuretics is ineffective.
Dosage and administration	The usual adult dosage is 7.5 mg of tolvaptan administered orally once per day.
Packaging	[PTP] 20 tablets (10 tablets × 2), [PTP] 100 tablets (10 tablets × 10) 
Date of approval for manufacture and sale	February 15, 2022
Date of NHI drug price listing	June 17, 2022
Date of launch	June 17, 2022
Price	491.60 yen/tablet
Manufactured and distributed by	Otsuka Pharmaceutical Factory, Inc.
Comarketed by	Otsuka Pharmaceutical Co., Ltd.

## Company Profile

### Otsuka Pharmaceutical Factory, Inc.

Established	:	October 7, 1969 (founded September 1, 1921)
Capital	:	80 million yen
Representative	:	Shinichi Ogasawara, President and Representative Director
Head Office	:	115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan
Employees	:	2,266 (as of December 31, 2021)
Business Description	:	Manufacture, sale, import and export of clinical nutrition products and other pharmaceutical products, medical devices, functional foods, etc.
URL	:	<a href="https://www.otsukakj.jp/en/">https://www.otsukakj.jp/en/</a>