

August 17, 2026

**Otsuka Pharmaceutical Factory obtains approval
for the manufacture and sale of the vasopressin V₂-receptor antagonist
“Tolvaptan OD tablets 30 mg Otsuka”**

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shuichi Takagi; hereinafter “Otsuka Pharmaceutical Factory”) announces that it has obtained approval today for the manufacture and sale of “Tolvaptan OD tablets 30 mg Otsuka” (nonproprietary name: tolvaptan; hereinafter “the Product”), a vasopressin V₂-receptor antagonist.

The Product is an authorized generic drug of “SAMSCA[®] OD Tablets 30 mg,” which was synthesized and developed by Otsuka Pharmaceutical Co., Ltd. (Head Office: Tokyo, Japan; President and Representative Director: Makoto Inoue), an Otsuka Group company. The Product has the same drug substance, additives, manufacturing method, and manufacturing site as SAMSCA[®] OD Tablets 30 mg.

In polycystic kidney disease, tolvaptan suppresses vasopressin-induced increases in intracellular cyclic adenosine monophosphate (cAMP), thereby inhibiting increases in kidney volume and renal cyst growth. The Product was approved for the indication of “slowing the progression of autosomal dominant polycystic kidney disease in patients with an increased kidney volume and a rapid rate of kidney volume increase.”

Otsuka Pharmaceutical Factory launched “Tolvaptan OD tablets 7.5 mg Otsuka” and “Tolvaptan OD tablets 15 mg Otsuka” in 2022. In April 2026, both products received approval for the additional indication of “slowing the progression of autosomal dominant polycystic kidney disease in patients with an increased kidney volume and a rapid rate of kidney volume increase.”

The addition of the Product to the lineup is expected to reduce the number of tablets patients need to take and thereby help reduce the burden associated with taking medication. Further details, including the launch timing of the Product, will be announced once they have been determined.

As a leading IV solution company, Otsuka Pharmaceutical Factory maintains an extensive network across a wide range of healthcare settings, from acute care to home healthcare, through regular contact with various clinical departments. Otsuka Pharmaceutical Factory 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.

Otsuka-people creating new products for better health worldwide

Product Information

Brand name	Tolvaptan OD tablets 30 mg Otsuka
Generic name	Tolvaptan
Indication	Slowing the progression of autosomal dominant polycystic kidney disease in patients with an increased kidney volume and a rapid rate of kidney volume increase.
Dosage and administration	The usual initial adult dosage of Tolvaptan is 60 mg per day as a split-dose oral regimen of 45 mg/15 mg (morning/evening). When Tolvaptan is tolerated at 60 mg per day for ≥ 1 week, the dose may be increased to 90 mg (60 mg/30 mg) per day and then to 120 mg (90 mg/30 mg) per day in a step-wise manner with a ≥ 1 -week interval between titrations. The dose may be adjusted, as appropriate, based on tolerability, but the maximum dose should not exceed 120 mg per day.
Packaging	 [PTP] 10 tablets (10 tablets $\times$ 1)
Date of approval for manufacture and sale	August 17, 2026
Manufactured and distributed by	Otsuka Pharmaceutical Factory, Inc.
Comarketed by	Otsuka Pharmaceutical Co., Ltd.

Corporate Profile

Otsuka Pharmaceutical Factory, Inc.

Incorporated	: October 7, 1969 (founded September 1, 1921)
Capital	: 40.08 billion yen
Representative	: Shuichi Takagi, President and Representative Director
Head Office	: 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan
Employees	: 2,432 (as of December 31, 2025)
Business Description	: Manufacture, sale, import and export of clinical nutrition products and other pharmaceutical products, medical devices, functional foods, etc.
URL	: https://www.otsukakj.jp/en/