

Santen Launches *COSOPT Mini Combination ophthalmic solution* for the Treatment of Glaucoma and Ocular Hypertension

June 24, 2015, Osaka, Japan – Santen Pharmaceutical Co., Ltd. announced today that it has launched *COSOPT Mini Combination ophthalmic solution* (generic name: dorzolamide hydrochloride/timolol maleate; hereinafter “*COSOPT Mini*”) for the treatment of glaucoma and ocular hypertension in the Japanese market.

COSOPT Mini is a preservative-free solution in single-dose sterile disposable vial with the same active ingredients as *COSOPT Combination ophthalmic solution* which contains *TRUSOPT ophthalmic solution 1%* (generic name: dorzolamide hydrochloride), a carbonic anhydrase inhibitor, and *TIMOPTOL ophthalmic solution 0.5%* (generic name: timolol maleate), a beta-adrenergic receptor blocker agent.

Glaucoma is a disease characterized by optic nerve disorder and progressive visual field defects due to increased intraocular pressure or other factors. Glaucoma is known as one of the leading causes of visual impairment (low vision and blindness). Because the optic nerve disorder and visual field disorder caused by glaucoma are essentially progressive and irreversible, early detection is required, and treatment of glaucoma is usually intended to lower intraocular pressure. Because glaucoma is a chronic and progressive disease, many patients receive life-long, combination treatment. Patients taking drugs long term and/or multiple drugs, often develop corneal epithelial disorder. For the patients having allergy to benzalkonium chloride, common preservative, and for the patients with corneal epithelial disorder, preservative-free drugs are required.

Preservative-free *COSOPT Mini* can be a useful treatment option allowing Santen to further contribute to improvement in patient quality of life.

Santen Pharmaceutical Co., Ltd. has no plans to revise its full-year financial forecasts because of the launch of *COSOPT Mini*.

Product Characteristics

- *COSOPT Mini* is a fixed dosed combination ophthalmic solution containing *TRUSOPT Ophthalmic Solution 1%* (generic name: dorzolamide hydrochloride) and *TIMOPTOL ophthalmic solution 0.5%* (generic name: timolol maleate) for the treatment of glaucoma and ocular hypertension.
- *COSOPT Mini* contains the same active ingredients and concentration as *COSOPT Combination ophthalmic solution*.
- *COSOPT Mini* is preservative-free and is packaged in single-dose disposable vials.

Product Outline

Product name	<i>COSOPT Mini Combination ophthalmic solution</i>
Generic name	Dorzolamide hydrochloride/timololmaleate
Dosage form	Aqueous ophthalmic solution
Indication	In the case that treatment with other glaucoma drugs is insufficient in patients with the following disease: glaucoma, ocular hypertension <Precautions Related to Indications and Use> Monotherapy treatment should be prioritized.
Dosage	Topical instillation, one drop at a time, twice daily
Storage method	Store at room temperature in a tight container, and protect from light
Package	0.4 mL/vial, plastic eye dropper vials × 90 (30 vials per one aluminum foil envelope × 3 envelopes)
Price	64.00 JPY per 0.4 mL vial
Insurance coverage	Insurance will cover this drug for the following patients: 1) those who are or believed to be highly sensitive to benzalkonium chloride, or 2) those who have corneal epithelial disorder.
Date of approval	March 10, 2015
Date of NHI price listing	May 29, 2015
Date of launch	June 24, 2015

Product Image



About Santen

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, sales, and marketing of pharmaceuticals. The company has bases in about 20 countries and delivers products in more than 70 countries. In Japan, Santen holds the No. 1 share in the prescription ophthalmic pharmaceutical market. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs. For more details, please see Santen's website (www.santen.com).

Santen Forward-looking Statements

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial conditions are subject to the effects of changes in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.