



***Alesion*[®] Eyelid Cream 0.5%, a new treatment for allergic conjunctivitis, goes on sale in Japan**
- World-first cream-type allergic conjunctivitis treatment
requiring just once daily administration to the upper and lower eyelids -

May 22, 2024, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (head office: Osaka; hereinafter Santen) and Mitsubishi Tanabe Pharma Corporation (head office: Osaka; hereinafter Mitsubishi Tanabe Pharma) have announced the launch of *Alesion*[®] Eyelid Cream 0.5%, (generic name: epinastine hydrochloride, development code: STN1011402; hereinafter *Alesion*[®] Cream), an allergic conjunctivitis treatment in Japan today. Both companies have already concluded a joint sales promotion contract for the product, which is sold in Japan by Santen. The product is the world's first cream-type allergic conjunctivitis treatment requiring just once daily administration to the upper and lower eyelids (the area around the eyes).

Alesion[®] Cream was developed by Santen as a new choice for the treatment of allergic conjunctivitis, a condition which is typically treated with anti-allergy eye drops (mediator release inhibitors and histamine H₁ receptor antagonists). Santen hopes that this new formulation will make it easier for patients to take their required dose, thereby improving patient adherence. The development of the product in a new cream formulation is also expected to help patients who find it difficult to take eyedrops receive their medicine more easily. The cream needs only to be applied directly with the fingertips to the upper and lower eyelids once a day for the product to prove effective.

Alesion[®] Cream's active ingredient is epinastine hydrochloride (a histamine H₁ receptor antagonist which suppresses the release of chemical mediators from mast cells) that was discovered and developed by Boehringer Ingelheim in 1975. Phase III clinical trials (Conjunctival Allergen Challenge trial; randomized, double-masked, placebo-controlled trial) carried out on patients in Japan during the asymptomatic phase confirmed that the product demonstrates superiority in comparison to a placebo eyelid cream in suppressing pruritus (intense itching) and conjunctival hyperemia (bloodshot eyes), the main symptoms of allergic conjunctivitis. In addition, a Phase III trial of the long-term administration of the product showed no serious adverse reactions, recording an incidence rate of 1.6% (2/124) for eyelid itchiness and 0.8% (1/124) for eyelid redness.

Alesion[®] Cream will be manufactured and sold by Santen. Based on the joint sales promotion contract announced on May 7, 2024, by Santen and Mitsubishi Tanabe Pharma, detailing of medical institutions on the product will be provided jointly by both companies. Santen will detail ophthalmic medical institutions, while Mitsubishi Tanabe Pharma will detail all other medical institutions. Under these arrangements, Santen, a company specializing in eye health, and Mitsubishi Tanabe Pharma, which sells allergy treatment

agent *Rupafin® Tablets 10 mg* and has access to medical institutions operating in a wide range of specialist fields, will facilitate the delivery of this new treatment option for allergic conjunctivitis to a larger number of medical institutions, thereby raising patients' quality of life (QOL).

Ippei Kurihara, who is the Head of Japan Business and Global Commercial Strategy at Santen, said "Santen has always placed importance on patient-centered formulation development. We have harnessed the know-how we built up through the development, manufacture and sale of the anti-allergic eyedrops "*Alesion® LX Ophthalmic Solution 0.1%*" and "*Alesion® Ophthalmic Solution 0.05%*" to develop a cream to be applied to the upper and lower eyelids (the area around the eyes) once a day. Many of the increasing number of allergic conjunctivitis patients in Japan experience lower QOL due to symptoms of the condition including itchy and bloodshot eyes. The release of this new product not only provides a new treatment choice for allergic conjunctivitis patients, it is also expected to reduce the frequency of eye itchiness, helping allergic conjunctivitis patients to reduce decline in QOL."

Yasutaka Kuragaki, who is the Head of Japan Pharmaceutical Business Division, at Mitsubishi Tanabe Pharma, said "Mitsubishi Tanabe Pharma sets the MISSION of 'Creating hope for all facing illness.' Mitsubishi Tanabe Pharma has been involved in information provision activities with the antiallergic eye drops "*Alesion® LX Ophthalmic Solution 0.1%*" and "*Alesion® Ophthalmic Solution 0.05%*". *Alesion® Cream* is a new formulation that is applied to the upper and lower eyelids once daily. Mitsubishi Tanabe Pharma will promote the proper use of *Alesion® Cream* through information provision activities so that it can become a promising option for patients with allergic conjunctivitis."

About *Alesion® Cream 0.5%*

Product name	<i>Alesion® Eyelid Cream 0.5%</i>
Generic name	Epinastine hydrochloride
Dosage form	White / off-white cream
Indication	Allergic conjunctivitis
Dosage	The standard dose is the once daily administration of an appropriate amount of the cream to the upper and lower eyelids
Storage	Room temperature
Packaging	2g tubes ×10
National Health Insurance price	0.5%1g 1,686.70 yen
Cautions required when supplying using NHI	None
Date of marketing approval	March 26, 2024

Date of NHI price listing	May 22, 2024
Date of launch	May 22, 2024

* *Alesion*[®] is a registered trademark of Boehringer Ingelheim KG.

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About Santen

As a specialized company dedicated to eye health, Santen aspires to contribute to the realization of “Happiness with Vision” by providing products and services to patients, consumers, and medical professionals around the world. Since its establishment, and guided by its CORE PRINCIPLE, “Tenki ni sanyo suru,” Santen has been committed to helping people maintain and improve their eye health for more than 130 years. Santen is engaged in the global research and development, manufacturing, and sales and marketing of pharmaceutical products in the field of eye care, supporting the eye health of approximately 50 million people in more than 60 countries and regions worldwide. Santen’s mission is to provide essential and significant value to patients and society in the prevention, diagnosis, and treatment of eye diseases through products and services created from its expertise in the ophthalmology field and from the patient’s perspective. To create a future in which as many patients as possible can lead happy and fulfilling lives, Santen is committed to doing its utmost to realize a society in which people around the world can experience “Happiness with Vision.”

For more information, please visit Santen’s website <https://www.santen.com/en>.

About Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation (MTPC), the pharma arm of Mitsubishi Chemical Group (MCG), is one of the oldest pharmaceutical companies in the world, founded in 1678, and focusing

on ethical pharmaceuticals. MTPC is headquartered in Doshomachi, Osaka, the birthplace of Japan's pharmaceutical industry. MCG has positioned health care as its strategic focus in its management policy, "Forging the future". MTPC sets the MISSION of "Creating hope for all facing illness". To that end, MTPC is working on the disease areas of central nervous system, immuno-inflammation, diabetes and kidney, and cancer. MTPC is focusing on "precision medicine" to provide drugs with high treatment satisfaction by identifying patient populations with high potential for efficacy and safety. In addition, MTPC is working to develop "around the pill solutions" to address specific patient concerns based on therapeutic medicine, including prevention of diseases, pre-symptomatic disease care, prevention of aggravation and prognosis. For more information, go to <https://www.mt-pharma.co.jp/e/>

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