

News Release

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Maruho Co., Ltd.

Maruho Receives Manufacturing and Marketing Approval for Primary Axillary Hyperhidrosis Treatment “Rapifort® Wipes 2.5%” in Japan

Osaka (Japan), January 20, 2022 – Maruho Co., Ltd. (“Maruho”, Head Office: Osaka, Japan, President and CEO: Atsushi Sugita) announces that it has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare for “Rapifort® Wipes 2.5%” (Japanese Accepted Name (JAN): glycopyrronium tosilate hydrate, hereinafter referred to as “the product”), for the treatment of primary axillary hyperhidrosis in Japan.

Primary local hyperhidrosis is a disease that causes a large amount of sweating in local areas such as the head/face, palms, soles, and underarms, regardless of the presence of heat or emotions, which interferes with daily life.¹

In particular when it occurs in the axilla (underarms), it is defined as primary axillary hyperhidrosis. Prevalence in Japan is 5.75%,² about 1 in 20 people have been reported to have primary axillary hyperhidrosis.

Excessive sweating affects a patient's daily life such as at school or work, causing considerable emotional stress.^{3,4,5}

In Japan, there are only a limited number of therapeutic agents covered by insurance indicated for the treatment of primary axillary hyperhidrosis, and new treatment options are required.

The product is a wipe formulation with a partial modification of the prescription of a topical agent developed by Dermira, Inc.* in the US (not approved in Japan). The active ingredient, glycopyrronium tosilate hydrate, reduces sweat production by blocking the activation of acetylcholine receptors in sweat glands. Sweat is suppressed by applying the drug solution to both underarms once a day using one sheet of non-woven fabric enclosed in one packet. Since it is a single-use wipe formulation, it can be used easily and hygienically.

In September 2016, Maruho entered an exclusive license agreement with Dermira, Inc. for development and commercialization in Japan. Maruho has been proceeding with development in Japan since that time.

Specializing in dermatology, Maruho hopes that this approval will lead to a new treatment option for primary axillary hyperhidrosis.

Product Profile

Brand Name	Rapifort® Wipes 2.5%
JAN	Glycopyrronium tosilate hydrate
Formulation/Dose	62.5mg of glycopyrronium tosilate hydrate in one packet (2.5g of drug solution)
Indication	Primary axillary hyperhidrosis
Dosage and Administration	Apply the drug solution to both underarms once a day using one sheet of non-woven fabric enclosed in one packet.

References

1. Japanese Dermatological Association Guidelines: Primary Local Hyperhidrosis Practice Guidelines 2015 Revised Edition, The Japanese Journal of Dermatology 2015; 125: 1379-1400
2. Fujimoto T, et al. Epidemiological study and considerations of primary focal hyperhidrosis in Japan: from questionnaire analysis. J Dermatol. 2013; 40: 886–90.
3. Yuichiro Oshima, Treatment of hyperhidrosis: in line with guidelines MB Derma. 220, 41-49 (2014)
4. Hamm H. et al., Primary focal hyperhidrosis: Disease characteristics and functional impairment. Dermatology. 212(2), 343-353 (2006)
5. Bahar R. et al., The prevalence of anxiety and depression in patients with or without hyperhidrosis (HH). J Am Acad Dermatol. 75(6), 1126-1133 (2016)

Note

*The rights to the product are currently owned by Journey Medical Corporation.

About Maruho

Maruho Co., Ltd. has its headquarters in Osaka and leads Japan in research and development, manufacturing and commercialization of dermatological products. Founded in 1915, Maruho has 1,546 employees (as of the end of September 2021), and net sales were approximately 87.03 billion yen in its fiscal year ended September 30, 2021. Pursuing its long-term corporate vision of “Excellence in Dermatology,” Maruho is striving to improve the health and quality of life of people all over the world. For more information, please visit <https://www.maruho.co.jp/english/>

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