

This material is an English translation of the press release announced on Mar 27, 2023 in Japanese, and the Japanese release is given priority about the content and the interpretation.

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Mar 27, 2023

**Notification of approval for manufacturing and marketing approval of  
APOHIDE® Lotion 20% in Japan  
(Primary palmar hyperhidrosis treatment drug, development code: HP-5070)**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as “Hisamitsu Pharmaceutical”) announces that it has obtained approval for manufacturing and marketing for APOHIDE® Lotion 20%, for the primary palmar hyperhidrosis treatment drug (Development code: HP-5070, generic name: oxybutynin hydrochloride, hereinafter referred to as “the product”) in Japan as of today.

Primary palmar hyperhidrosis is a disorder in which excessive bilateral sweating from the palms is observed, and is known to be a major factor in reducing the quality of life and labor efficiency in various aspects of school and social life, as it significantly interferes with social activities (e.g., handshaking), paper work, and operation of electronic devices<sup>1)</sup>.

The product is a topical formulation developed using Hisamitsu’s TDDS (Transdermal Drug Delivery System) technology, and the first drug in Japan to demonstrate efficacy and safety in the Phase III clinical study conducted in patients with primary palmar hyperhidrosis.

With this approval, Hisamitsu Pharmaceutical expects the product, which is effective when applied to the palms once a day before bedtime, will be a new option for the treatment of primary palmar hyperhidrosis.

Hisamitsu Pharmaceutical will contribute to improving the quality of life of patients with primary palmar hyperhidrosis by providing proper information of the product.

Reference:

Trade name	APOHIDE® Lotion 20%
Active pharmaceutical ingredient	Oxybutynin hydrochloride
Indications	Primary palmar hyperhidrosis
Dosage and administration	Apply an appropriate amount to both palms once a day before bedtime.
Precautions concerning dosage and administration	One application should be equivalent to five pump strokes per both palms.
Packaging	4.5mL (plastic container) x 20 bottles

**【Source】**

- 1) Japanese Dermatological Association Guidelines: Guidelines for the Treatment of Primary Focal Hyperhidrosis, revised 2023.