

News Release

February 24, 2023
Maruho Co., Ltd.

Maruho Receives Manufacturing and Marketing Approval for a Partial Change of the Indication and Dosage/Administration for Anti-herpes Virus Agent “Amenalief[®] Tab. 200mg” for the Treatment of Recurrent Herpes Simplex in Japan

Osaka (Japan), February 24, 2023 – 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, Labor and Welfare for a partial change of the indication and dosage/administration for anti-herpes virus agent “Amenalief[®] Tab. 200mg” (JAN/INN: amenamevir; hereinafter referred to as “the product”) for the treatment of recurrent herpes simplex in Japan.

Herpes simplex is a general term for infectious diseases caused by the herpes simplex virus that infects the skin and mucous membranes (lips, eyes, genitals, etc.). Common types include labial herpes and genital herpes.

Recurrent herpes simplex is a disease that develops when the herpes simplex virus that has been latently infected in the ganglia after a primary infection, is reactivated by stimuli such as stress or a weakened immune system. Additionally, it is characterized by repeated recurrence of symptoms, and many patients experience discomfort such as itching and tingling before skin symptoms such as erythema (redness), papules and blisters develop.

The partial change of the indication and dosage/administration approval received today is recognized as “Patient Initiated Treatment” (PIT) for patients with recurrent herpes simplex when they become aware of the initial symptoms.¹⁾

Early treatment is possible by taking the prescribed 1200mg of this drug once after meals within 6 hours after the appearance of the initial symptoms of recurrent herpes simplex. It is hoped that this drug will be more convenient for patients since only one dose is required.

Maruho, specializing in dermatology, will strive to further contribute to patients and medical professionals by providing new options for the treatment of recurrent herpes simplex.

Note

The information contained in this news release in regard to pharmaceutical and developmental products is not intended for the purpose of promotion, advertising or medical advice.

Product Profile

Brand Name	Amenalief® Tab. 200mg
JAN/INN	Amenamevir
Formulation/Dose	Film coated tablets containing 200mg of amenamevir in 1 tablet
Indication (Additional content is underlined)	Herpes Zoster <u>Recurrent Herpes Simplex</u>
Dosage and Administration (Additional content is underlined)	<u>(Herpes Zoster)</u> General administration for adults is 400mg of amenamevir once a day administered orally after a meal. <u>Recurrent Herpes Simplex)</u> <u>General administration for adults is 1200mg of amenamevir administered orally after a meal.</u>

References

- 1) Shinichiro Yasumoto, Patient-initiated-treatment (PIT) in the management of patients with recurrent herpes simplex, Japanese Journal of Clinical Dermatology, 74 (5), 135 (2020)

About Amenalief Tab.

Amenalief Tab. is an oral anti-herpes virus agent with a novel mechanism of action containing the non-nucleic acid analog amenamevir, created in Japan by Astellas Pharma Inc. By inhibiting the activity of the helicase-primase complex, an essential enzyme for DNA replication of the herpesvirus, it exhibits antiviral activity by suppressing double-stranded DNA cleavage and RNA primer synthesis. Maruho manufactures and commercializes the product in Japan and it has been used for the treatment of herpes zoster since 2017.

Maruho's initiatives for disease caused by herpes

Maruho is working to help patients suffering from herpes labialis and genital herpes to understand the diseases correctly and take appropriate measures in the event of a recurrence.

Through the comprehensive herpes information site "What's herpes?" the causes and remedies for cold sores and genital herpes are explained.

(<https://www.maruho.co.jp/kanja/herpes/>)

(As Maruho markets treatments for customers in Japan, the information is only provided in Japanese).

About Maruho

Maruho Co., Ltd. has its head office in Osaka and leads Japan in research and development, manufacturing and commercialization of dermatological products. Founded in 1915, Maruho has 1,547 employees (as of the end of September 2022), and net sales were approximately 85.67 billion yen in its fiscal year ended September 30, 2022. 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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