

June 6, 2018

Press Release

Nobelpharma Co., Ltd.

Launch of RAPALIMUS[®] GEL 0.2%
SAKIGAKE Designation & Orphan Drug Designation
Treatment for Angiofibroma in Tuberous Sclerosis Complex

Nobelpharma Co., Ltd. (Head Office: Chuo-ku, Tokyo; President and CEO: Jin Shiomura) announces the launch of RAPALIMUS[®] GEL 0.2% (general name: sirolimus), a drug for the treatment of angiofibroma in tuberous sclerosis complex (TSC).

This drug was the first to be awarded the SAKIGAKE designation in October 2015, then was designated as an orphan drug in December 2015, and obtained marketing approval on March 23, 2018.

TSC is a rare inheritable disease that can cause developmental disorders or tumor lesions on a variety of organs throughout the body such as the brain, skin and kidneys. Skin lesions such as angiofibroma on the face frequently appear, and because the condition is observable from adolescence, it causes pain for patients as well as considerable reduction in the quality of their lives. This drug is the first in the world to be approved as topical agent to treat angiofibroma in TSC, and we are confident that it will contribute to the improvement of the quality of the lives of patients suffering from TSC in Japan. Nobelpharma will continue to contribute to society by providing drugs and medical devices for unmet needs in the future.

【Contact】

Nobelpharma Co., Ltd.

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【Product Profile】

Brand Name: RAPALIMUS® GEL 0.2%

Generic Name: sirolimus

Indication: angiofibroma associated with tuberous sclerosis complex

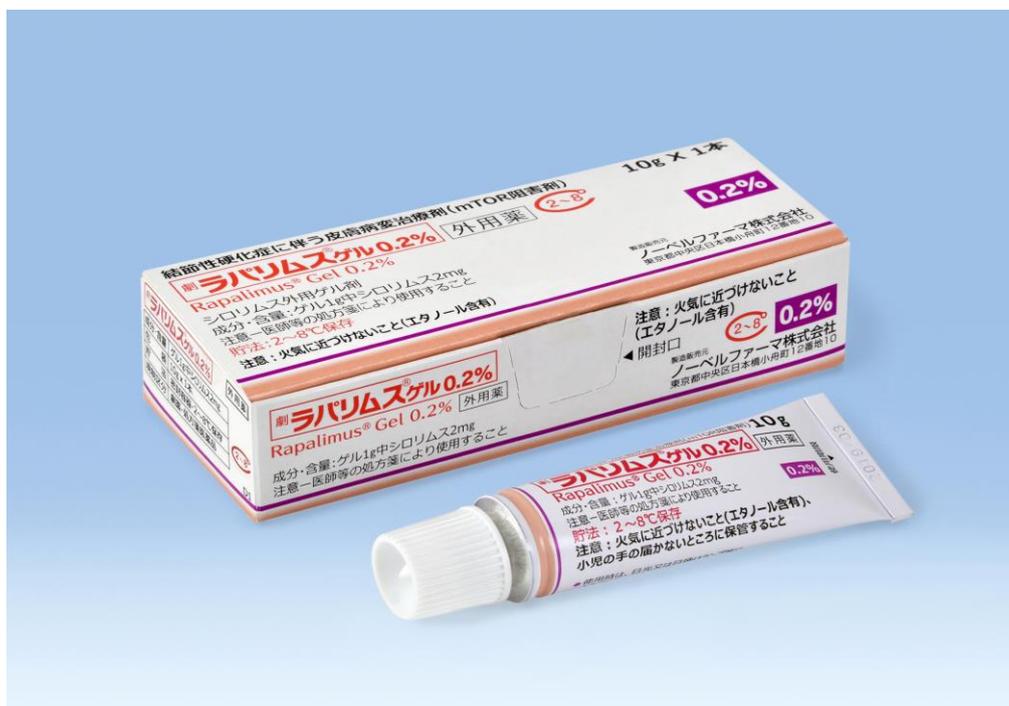
Package: 10g tube

Dosage and Administration: Ordinarily, twice per day, an appropriate amount to be applied to affected area.

NHI Drug Price: 3,855 yen (0.2% 1g)

Manufactured and sold by: Nobelpharma Co., Ltd.

Product Website: <http://nobelpark.jp/>



About Nobelpharma

Nobelpharma has been contributing to the provision of necessary treatments for overlooked diseases through development of medicines since 2003. Our development priority is on medicines and medical devices for unmet needs that are strongly desired by patients associations and medical associations. Currently, we have obtained marketing approval for 14 products, mostly focused on medicines and medical devices for unmet needs, and of those 10 products have received the orphan drug designation.