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Astellas Educates and Informs Physicians and Patients on Changes to Protopic Label in the US

Recently, new information was added to the US labeling for the class of topical calcineurin inhibitors, or TCIs, which includes Protopic[®] (tacrolimus) Ointment and pimecrolimus cream. The new language, developed in collaboration with the US Food and Drug Administration, includes a boxed warning that states that although no causal relationship has been established, rare cases of malignancies (e.g., skin and lymphoma) have been reported in patients treated with TCIs. The updated labeling also states that the long term safety of TCIs has not been established and provides additional directions for the appropriate use of Protopic. Additionally, Astellas is issuing a new Medication Guide for patients who receive a prescription for Protopic that instructs them on the proper use of the medication and encourages them to consult with their healthcare professionals should they have questions about the medicine.

Protopic remains an important treatment option for children age two and older and adults with moderate to severe eczema. Protopic is safe and effective when used in a manner consistent with its label. As part of its continued commitment to provide healthcare professionals and patients with timely and accurate clinical information to assist in making informed treatment decisions, Astellas is making the label available to them as well as educating and informing patients, physicians, and other organizations about the updated label and the appropriate use of Protopic.

Communications efforts include making the new label information available on the Protopic website (www.protopic.com), issuing a “Dear Healthcare Professional” letter which encloses the updated label as well as reaching out to leading patient advocacy organizations, such as the National Eczema Association for Science and Education (NEASE), and professional medical societies, including the American Academy of Dermatology (AAD) and the American Academy of Asthma Allergy and Immunology (AAAAI). Astellas’ goal is to provide these organizations, who continue to recognize TCIs as an important treatment option, with information to educate their members about the labeling changes.

ABOUT ECZEMA

Eczema is the term for a group of medical conditions that cause the skin to become inflamed or irritated. The most common type of eczema is known as atopic dermatitis, or atopic eczema. It affects about 3% of adults and children in the U.S.¹

¹ <http://www.webmd.com/content/article/61/67471.htm>

ABOUT PROTOPIC

More than 19,000 patients with eczema, including 7,600 children, participated in studies on the safety and efficacy of Protopic. Since approval by the Food and Drug Administration (FDA) in December 2000, an estimated 1.7 million patients in the United States and 3 million patients worldwide have been treated with Protopic.

Protopic was approved in December 2000 as the first in a new class of prescription drugs called topical calcineurin inhibitors, or TCIs, to be developed in more than 40 years for the treatment of eczema. In addition to the U.S., Protopic is currently marketed in over 45 countries worldwide, including Japan, Canada, and countries in Europe, Asia and Latin America.

Protopic Ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated as *second-line therapy* for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable. Protopic Ointment is not indicated for children younger than 2 years of age.

The most common adverse events associated with the use of Protopic Ointment included skin burning, pruritus, flu-like symptoms and headache. Patients should minimize or avoid natural or artificial sunlight exposure. Skin infections should be cleared prior to application, and there may be an increased risk of certain skin infections. Protopic Ointment is contraindicated in patients who are allergic to tacrolimus or any other ingredients. For full prescribing information, go to www.protopic.com.

ABOUT ASTELLAS

Astellas Pharma US, Inc., a US subsidiary of Tokyo-based Astellas Pharma Inc., is a research-based pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Established on April 1, 2005, the company was formed through a merger that combined the outstanding research, development and marketing capabilities of Fujisawa Pharmaceutical Co., Ltd. and Yamanouchi Pharmaceutical Co., Ltd. Astellas ranks among the top 20 pharmaceutical companies in the world and will continue to grow as a competitive company in the world pharmaceutical market. For more information on Astellas Pharma US, Inc., go to www.astellas.com/us.