



MAYNE PHARMA LAUNCHES FABIOR[®] AND SORILUX[®] IN THE UNITED STATES

Jan. 11, 2017, Greenville, North Carolina: Mayne Pharma Inc. is pleased to announce the launch of Fabior[®] (tazarotene) Foam, 0.1% and Sorilux[®] (calcipotriene) Foam, 0.005% in the United States by Mayne Pharma's Specialty Brands division.

These foam products, previously marketed by GlaxoSmithKline (GSK), were acquired by Mayne Pharma in August 2016 and are complementary dermatology products to Doryx[®], the first branded product launched by Mayne Pharma's Specialty Brands division in the United States in May 2015.

Fabior is a patent-protected foam product indicated for the topical treatment of acne, the most prevalent skin disease in the United States affecting as many as 50 million people of all ages¹. Fabior is part of the single active retinoid market in which 5 million prescriptions are written annually. This market is significantly larger than the oral antibiotic acne market that Doryx participates in as topical products are used more frequently by acne patients across the disease spectrum ranging from mild and moderate to severe acne cases.

Sorilux is a patent-protected foam product indicated for the topical treatment of plaque psoriasis of the scalp and body affecting up to 6 million Americans each year¹. Sorilux is part of the single active Vitamin D market in which 0.5 million prescriptions are written annually.

Mayne Pharma's CEO Scott Richards said, "Both Fabior and Sorilux are a great strategic fit with the existing Doryx franchise and participate in attractive and growing markets. Both products are well differentiated with compelling clinical data that physicians and patients will appreciate. The foam delivery platform has a well-established reputation with dermatologists due to ease of application, especially in hair-bearing areas and under clothing. With a focused and sustained marketing effort, we can further support the needs of patients and dermatologists and these products will become important treatment options for people with acne and plaque psoriasis.

"We have met our planned commercial launch timing and have also now internalized our 60-person dermatology sales team from a third-party contract sales organization, which is expected to provide cost savings, improved ability to attract and retain talent, improved performance management and, ultimately, improved sales force effectiveness. Over time, we expect to commercialize complementary product innovations in dermatology and other specialty therapeutic areas utilizing the company's internal pipeline or via targeted in-licensing and/or product acquisitions."

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¹ American Academy of Dermatology





About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialize branded and generic pharmaceuticals, providing patients with access to better and more affordable medicines. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialized in numerous products that have been marketed around the world.

Mayne Pharma has two product development and manufacturing facilities based in Greenville, North Carolina, USA, and Salisbury, Australia, with expertise in the formulation of complex oral dose forms including highly potent compounds, controlled substances, modified-release products and inherently unstable compounds.

About Fabior®

Fabior is a retinoid in a topical foam formulation for the treatment of acne vulgaris in patients 12 years of age and older. Fabior foam is not for oral, ophthalmic or intravaginal use. Full prescribing information for Fabior is available [here](#).

About Sorilux®

Sorilux foam contains calcipotriene, a synthetic vitamin D3 analogue. It is indicated for the topical treatment of plaque psoriasis of the scalp and body in patients aged 18 years and older. Plaque psoriasis is a chronic, non-contagious, inflammatory skin condition that appears as red patches covered with silvery flakes often found on the elbows, scalp and knees but can also affect other parts of the body. Full prescribing information for Sorilux is available [here](#).

Selected Safety Information about Fabior® Foam.

Fabior® Foam is contraindicated in pregnancy. Fabior® Foam may cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued and the patient apprised of the potential hazard to the fetus. Fabior® Foam should be used with caution in patients with history of local tolerability reactions or local hypersensitivity. Use Fabior® Foam with caution with other topical medicines because a cumulative irritant effect may occur. Instruct the patient to avoid exposure to sunlight, sunlamps and weather extremes and to wear sunscreen daily. The propellant in Fabior® Foam is flammable. Instruct the patient to avoid fire, flame and/or smoking during and immediately following application. Most common adverse reactions reported at an incidence $\geq 6\%$ are application site irritation, application site dryness, application site erythema and application site exfoliation. Avoid concomitant dermatological medications and cosmetics that have a strong drying effect.

Selected Safety Information about Sorilux® Foam.

Sorilux® Foam should not be used by patients with known hypercalcemia. The propellant in Sorilux® Foam is flammable. Instruct the patient to avoid fire, flame and smoking during and immediately following application. Transient, rapidly reversible elevation of serum calcium has occurred with use of calcipotriene. If elevation in serum calcium outside the normal range should occur, discontinue treatment until normal calcium levels are restored. Avoid exposure of the treated areas to natural or artificial sunlight. Adverse reactions reported in $\geq 1\%$ of subjects treated with Sorilux® Foam and at a higher incidence than subjects treated with vehicle were application site erythema and application site pain.

To report a suspected adverse reaction from one of our products, please contact Mayne Pharma at 1-844-825-8500 or maynepharmamc@dlss.com, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

