



MAYNE PHARMA LAUNCHES LEXETTE™ (HALOBETASOL PROPIONATE) FOAM 0.05% IN THE UNITED STATES

13 February 2019, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of LEXETTE™ (halobetasol propionate) Foam 0.05% in the United States.

LEXETTE, the conditionally-acceptable trade name for halobetasol foam is a new formulation of halobetasol, a potent topical corticosteroid indicated for the treatment of plaque psoriasis in adult patients. LEXETTE received approval from the US Food and Drug Administration (FDA) in May 2018 with three years of marketing exclusivity.

Plaque psoriasis affects approximately 7.5 million Americans with potent topical corticosteroids prescribed to approximately 80% of psoriasis patients diagnosed¹. LEXETTE is part of the US\$600m potent topical corticosteroid market for which 8 million prescriptions are written annually².

Mayne Pharma's CEO, Mr Scott Richards said "LEXETTE is an elegant foam formulation that will give psoriasis patients more treatment options. The foam delivery platform has a well-established reputation with dermatologists due to ease of application and lack of greasiness and stickiness, especially in hair-bearing areas and under clothing. LEXETTE will be supported by our existing psoriasis-focused sales team who will now be able to offer a potent steroid along with steroid-free SORILUX® Foam, which are both commonly used in psoriasis treatment protocols."

Mayne Pharma directly markets more than 60 products in the US including four branded dermatology products FABIOR® (tazarotene) Foam, SORILUX (calcipotriene) Foam, DORYX® MPC (doxycycline hyclate) delayed-release tablets and LEXETTE (halobetasol propionate) Foam. The Company recently received approval for TOLSURA™ (SUBA®-itraconazole) capsules used to treat certain fungal infections which it also recently launched.

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¹ American Academy of Dermatology Association, Company sponsored primary research

² IQVIA NSP and TRx MAT Nov 2018



About Mayne Pharma

At Mayne Pharma we believe that everyone deserves medicines that are better, safe and more affordable. That's why our people are determined to create innovative products and services for our changing world.

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialize branded and generic pharmaceuticals. 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 Salisbury, Australia and Greenville, USA with expertise in formulation of complex oral and topical dose forms including potent compounds, modified-release products and inherently unstable compounds.

About Lexette™ (halobetasol propionate) foam, 0.05%

LEXETTE (halobetasol propionate) Foam is a potent corticosteroid indicated for the topical treatment of plaque psoriasis in patients eighteen years of age and older. The proposed trade name LEXETTE™, is conditionally acceptable to the FDA.

LEXETTE Foam was evaluated for the treatment of moderate to severe plaque psoriasis in two multicentre, randomised, double-blind, vehicle-controlled studies. These studies were conducted in 560 subjects with plaque psoriasis involving between 2% and 12% body surface area. A foam vehicle can have many benefits including being absorbed quickly without residue or greasiness and being easy to apply to both hair-bearing and non-hair bearing skin.

Important Safety Information

LEXETTE Foam is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Systemic effects of topical corticosteroids may include reversible HPA axis suppression, with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment of the topical corticosteroid. The potential for hypothalamic-pituitary adrenal (HPA) suppression with LEXETTE Foam was evaluated in a study of 25 adult subjects with moderate to severe plaque psoriasis involving $\geq 15\%$ of their body surface area. LEXETTE Foam produced laboratory evidence of HPA axis suppression when used twice daily for two weeks in 6 out of 25 (24%) adult subjects with plaque psoriasis. Recovery of HPA axis function was generally prompt with the discontinuation of treatment.

Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to topical corticosteroids.

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids, including LEXETTE Foam. Some local adverse reactions may be irreversible. Use of topical corticosteroids may increase the risk of posterior subcapsular cataracts and glaucoma.

To report SUSPECTED ADVERSE REACTIONS, contact at Mayne Pharma at 1-844-825-8500 or FDA at 1 800-FDA-1088 or www.fda.gov/medwatch.

For more information about LEXETTE, please refer to the prescribing information available [here](#).