

Bryhali[™] (halobetasol propionate) – New drug approval

- On November 7, 2018, [Bausch Health](#) and [Ortho Dermatologics](#) announced the FDA approval of [Bryhali \(halobetasol propionate\)](#) lotion, for the topical treatment of plaque psoriasis in adults.
- Halobetasol propionate is also available generically as a [cream](#) and [ointment](#); and brand name 0.05% lotion ([Ultravate](#)[®]). [Mayne will be launching](#) a [foam](#) formulation in early 2019.
 - Halobetasol propionate cream and ointment are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
 - Ultravate and halobetasol propionate foam are indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.
- The efficacy of Bryhali was demonstrated in two double-blind studies conducted in 430 patients with moderate to severe plaque psoriasis. Patients applied Bryhali or vehicle to affected areas once daily for 8 weeks. The primary efficacy endpoint was the proportion of patients with treatment success at week 8. Treatment success was defined as at least a 2-grade improvement from baseline in investigator global assessment (IGA) score and an IGA score equating to clear or almost clear.
 - The IGA treatment success at week 8 in the first study was 37% for the Bryhali treated patients vs. 8% for the vehicle treated patients.
 - In the second study, the IGA treatment success at week 8 was 38% vs. 12% for the Bryhali and vehicle treated patients, respectively.
- Warnings and precautions of Bryhali include hypothalamic-pituitary-adrenal axis suppression, local adverse reaction, ophthalmic adverse reactions, concomitant skin infections, and allergic contact dermatitis.
- The most common adverse effects (≥ 1%) with Bryhali use were upper respiratory tract infection, application site dermatitis, and hyperglycemia.
- The recommended dosage for Bryhali is to apply a thin layer of lotion to affected areas and rub in gently once daily.
 - Treatment beyond 8 weeks is not recommended, and the total dosage should not exceed approximately 50 g per week. Treatment should be discontinued if control is achieved before 8 weeks.
 - Occlusive dressings should not be used with Bryhali unless directed by a physician.
 - Bryhali should not be used on the face, groin, or in the axillae.
 - Bryhali is not for oral, ophthalmic, or intravaginal use.
- Ortho Dermatologics plans to launch Bryhali later this month. Bryhali will be available as a 0.01% lotion.