

Wynzora® (calcipotriene/betamethasone dipropionate) – New drug approval

- On July 22, 2020, MC2 Therapeutics announced the FDA approval of Wynzora
 (calcipotriene/betamethasone dipropionate) cream, for the topical treatment of plaque psoriasis in patients 18 years of age and older.
- The combination of calcipotriene/betamethasone is also available as branded Enstilar® topical foam and generically as a topical suspension.
 - Enstilar and the generically available topical ointment are approved for plaque psoriasis in patients 12 years and older.
 - The topical suspension formulation is approved for plaque psoriasis of the scalp and body in patients 12 years and older.
- The efficacy of Wynzora was established in a randomized, vehicle and active-comparator controlled study in 794 adult patients with mild to moderate plaque psoriasis. Patients were randomized to 1 of 3 treatment groups: Wynzora cream, vehicle cream, or calcipotriene/ betamethasone dipropionate topical suspension. The primary 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 the Physician's Global Assessment (PGA) score and an PGA score equating to "clear" or "almost clear".
 - The primary endpoint was met in 37.4% of patients receiving Wynzora vs. 3.7% of patients receiving placebo (difference 33.7; 95% CI: 27.4, 40.0).
 - Wynzora cream was non-inferior to calcipotriene/betamethasone dipropionate topical suspension for the primary endpoint.
- Warnings and precautions for Wynzora include hypercalcemia and hypercalciuria; effects on endocrine system; allergic contact dermatitis with topical corticosteroids; allergic contact dermatitis with topical calcipotriene; and ophthalmic adverse reactions.
- The most common adverse reactions (> 1%) with Wynzora use were upper respiratory infection, headache, and application site irritation.
- The recommended administration of Wynzora is to apply to affected areas once daily for up to 8 weeks.
 - More than 100 grams per week should not be used.
 - Therapy should be discontinued when control is achieved.
- MC2 Therapeutics' launch plans for Wynzora are pending. Wynzora will be available as a topical cream containing 0.005% calcipotriene and 0.064% betamethasone dipropionate.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2020 Optum, Inc. All rights reserved.