

## 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 ointment](#) and [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.