# CLINICAL UPDATE

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| **Brand Name** | Wynzora® |
| **Generic Name** | calcipotriene and betamethasone dipropionate |
| **Drug Manufacturer** | MC2 Therapeutics Ltd |

## Clinical Update

### TYPE OF CLINICAL UPDATE

New Brand

### FDA APPROVAL DATE

July 20, 2020

### LAUNCH DATE

N/A

### REVIEW DESIGNATION

Standard

### TYPE OF REVIEW

New Drug Application (NDA): 213422

### DISPENSING RESTRICTIONS

N/A

## Overview

### INDICATION(S) FOR USE

Wynzora® Cream is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.

### MECHANISMS OF ACTION

Wynzora® Cream combines the pharmacological effects of calcipotriene as a synthetic vitamin D3 analog and betamethasone dipropionate as a synthetic corticosteroid. However, while their pharmacologic and clinical effects are known, the exact mechanisms of their actions in plaque psoriasis are unknown.

### DOSAGE FORM(S) AND STRENGTH(S)

Cream: 0.005%/0.064%

### DOSE & ADMINISTRATION

- Apply Wynzora® Cream to affected areas once daily for up to 8 weeks.
- Discontinue therapy when control is achieved.
- Do not use more than 100 g per week.
- Do not use with occlusive dressings unless directed by a physician.
- Avoid use on the face, groin, or axillae, or if skin atrophy is present at the treatment site.
- Not for oral, ophthalmic, or intravaginal use.

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## EFFICACY

The safety and efficacy of Wynzora® Cream were evaluated in a randomized, multicenter, vehicle and active comparator controlled, clinical trial (NCT03308799) in adult subjects with mild to moderate plaque psoriasis. In the trial, 794 subjects were randomized to 1 of 3 treatment groups: Wynzora® Cream, vehicle cream, or calcipotriene/betamethasone dipropionate topical suspension, 0.005%/0.064%. The majority of subjects in the trial (81.7%) had disease of moderate severity at baseline, while 18.3% of subjects had disease of mild severity. Disease severity was determined by a 5-grade Physician's Global Assessment (PGA) scale.

The primary efficacy endpoint was the proportion of subjects with treatment success at Week 8. Treatment success was defined as at least a 2-grade improvement from baseline in the PGA score and a PGA score equating to "clear" or "almost clear". Other evaluated outcomes included reduction in itch as defined by at least a 4-point improvement in the 11-point peak pruritus numeric rating scale (NRS) from baseline to Week 4.

**Primary Efficacy Outcome at Week 8**

| | WYNZORA Cream (N=342) | Vehicle Cream (N=115) |
|---|---|---|
| PGA of Clear or Almost Clear And ≥2-grade Improvement | 37.4% | 3.7% |
| Difference from Vehicle (95% CI) | 33.7% (27.4%, 40.0%) | |

Wynzora® Cream was non-inferior to calcipotriene/betamethasone dipropionate topical suspension, 0.005%/0.064% for the primary endpoint of treatment success at Week 8 [Difference (95% CI): 14.6% (7.6%, 21.6%)].

Among subjects who had at least a peak pruritus NRS score of 4 at baseline, there was a higher percentage of subjects that achieved at least a 4-point improvement from baseline on the peak pruritus NRS score at Week 4 in the Wynzora® Cream group compared to the vehicle cream group (60.3% vs. 21.4%).