# When plaque psoriasis is out of reach<sup>1</sup>...



## A spray that feels like a lotion

## For mild to moderate plaque psoriasis in adults

## **IMPORTANT SAFETY INFORMATION**

## **Warnings and Precautions**

**Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression and Other Unwanted Systemic Glucocorticoid Effects**: SERNIVO Spray can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency during or after treatment. Factors that predispose to HPA axis suppression include the use of high-potency corticosteroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. Evaluation for HPA axis suppression may be done by using the adrenocorticotropic hormone (ACTH) stimulation test. If HPA axis suppression is documented, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent corticosteroid. Systemic effects of topical corticosteroids may also manifest as Cushing's syndrome, hyperglycemia, and glucosuria. These events are rare and generally occur after prolonged exposure to larger than recommended doses, particularly with high-potency topical corticosteroids.

### Please see Important Safety Information throughout.

## **Pooled Analysis of Phase 3 Studies**

## **Demonstrated efficacy that** patients will notice<sup>2</sup>



NDC 68040-714-28

120 ml Rx Only



Both treatments were well-tolerated. The majority of treatment emergent adverse effects were mild with the most commonly reported across all groups at day 28 being application site pruritus (6% Sernivo Spray/9.4% vehicle) and pain (2.3% Sernivo Spray/3.9% vehicle)<sup>2</sup>

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## **A Significant Difference** by Day 8

Sernivo Spray was significantly superior to vehicle in achieving treatment success at Day 8 as well as Day 15 and Day 29<sup>2</sup>



- Data analysis on pooled data from two multicenter, randomized, double-blind, vehicle controlled clinical trials
- IGA score of 3 (moderate)
- almost clear) and at least a 2 grade reduction from baseline

• Subjects had a body surface area (BSA) between 10% - 20% and an

Treatment success defined as having an IGA score of 0 or 1 (clear or

## The efficacious betamethasone spray that feels like a lotion





LOTION LIKE FEEL<sup>3,5</sup> Patented oil-in-water emulsion

HARD-TO-REACH AND/OR WIDESPREAD AREAS<sup>1</sup> Thin, consistent easy spray application<sup>1</sup>



DAYS Significant improvements observed as soon as Day 8 (in pooled data analysis)<sup>2</sup>

## **DIRECTIONS FOR USE**

Apply to the affected skin areas twice daily. Rub in gently. Approved to use for up to 4 weeks

### **INDICATIONS AND USAGE**

SERNIVO Spray is a corticosteroid indicated for the treatment of mild to moderate plaque psoriasis in patients 18 years of age and older.

### **DOSAGE AND ADMINISTRATION**

- Shake well before use.
- Apply SERNIVO Spray to the affected skin areas twice daily and rub in gently.
- Use SERNIVO Spray for up to 4 weeks of treatment. Treatment beyond 4 weeks is not recommended.
- Discontinue SERNIVO Spray when control is achieved.
- Do not use if atrophy is present at the treatment site.
- Do not bandage, cover, or wrap the treated skin area unless directed by a physician.
- Avoid use on the face, scalp, axilla, groin, or other intertriginous areas.
- SERNIVO Spray is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

## **ADVERSE REACTIONS**

The most common adverse reactions (> 1%) are application site reactions, including pruritis, burning and/or stinging, pain, and atrophy.

## To report SUSPECTED ADVERSE REACTIONS, contact Primus Pharmaceuticals, Inc. at 1-480-483-1410 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**References: 1.** Wozel G. *Clin Dermatol.* 2008;26(5):448–459. **2.** Gold LS, Jackson JM, Knuckles MLF, Weiss JS. *J Drugs Dermatol.*2016;15(3):334-342 **3.** Jackson J, Grove G, Allenby K, Houser T. Poster presented at Winter Clinical, Kona, HI, January 13-18, 2017. **4.** Sernivo [package insert] Primus Pharmaceuticals, Inc. 2021. **5.** Fowler J, Sidgiddi S, Allenby K. Poster presented at Winter Clinical, Kona, HI, January 13-18, 2017.

## Please see Important Safety Information throughout Full Prescribing information at www.sernivorx.com

