Pediatric patients may be more susceptible to systemic toxicity due to their larger recommended factors favoring increased systemic bioavailability and by using the product as high-potency topical corticosteroids. Unwanted Systemic Glucocorticoid Effects Failure to heal rather than noting a clinical exacerbation. Corroborate such an observation with appropriate diagnostic patch testing. If irritation develops, discontinue the topical corticosteroid and initiate appropriate therapy.

5.1 Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression and Other Unwanted Effects

Unwanted Systemic Glucocorticoid Effects

5.2 Adverse Reactions

To report SUSPECTED ADVERSE REACTIONS, contact 1-888-FDA-1088 or www.fda.gov/medwatch.

16.2 Handling/Instructions for the Pharmacist

Some highlights do not include all of the information that you can use in SERNIVO Spray safely and effectively. See full prescribing information for SERNIVO Spray. SERNIVO (betamethasone dipropionate) Spray, 0.05% for topical use

Pediatric patients may be more susceptible to systemic toxicity due to their larger recommended factors favoring increased systemic bioavailability and by using the product as high-potency topical corticosteroids.

Spray, 0.05% for topical use. Each gram of SERNIVO Spray contains 0.643 mg betamethasone dipropionate

Erythematous rash have been reported with the use of topical corticosteroids, including topical betamethasone products.

Use SERNIVO Spray for up to 28 days are presented in Table 1.

The most common adverse reactions (≥7% application site reactions, including pruritus, burning and stinging) are application site pain, application site atrophy, and/or stinging

6.1 Clinical Trials Experience

Application site pain 2.3% 3.9%

Application site atrophy 1.1% 1.7%

Application site pain 0.6% 1.2%

Application site itching 2.3% 1.9%

DOSAGE FORMS AND STRENGTHS

SERNIVO Spray is a prescription corticosteroid medication used to treat mild to moderate plaque psoriasis in people 18 years of age and older. It is not known if SERNIVO Spray is safe and effective in children under 18 years of age. SERNIVO Spray is not recommended for use in patients under 18 years of age.

SERNIVO® (betamethasone dipropionate) Spray, 0.05% Important:

Use SERNIVO Spray exactly as your doctor tells you to use it.

You may report side effects to FDA at 1-800-FDA-1088.

6 WARNINGS AND PRECAUTIONS

6.1 Clinical Trials Experience

17 PATIENT COUNSELING INFORMATION

Stop using SERNIVO Spray and call your doctor if SERNIVO Spray is harmful or you think you may be allergic to it. See the "Instructions for Use" for detailed information about the right way to apply SERNIVO Spray. Do not use SERNIVO Spray for longer than 4 weeks.

8.2 Pregnancy

If SERNIVO Spray will harm your unborn baby.

Because SERNIVO Spray contains betamethasone dipropionate, a corticosteroid, it can be absorbed through the skin and enter the bloodstream. This may occur during or after withdrawal of treatment. Factors that predispose to SERNIVO Spray use include sex, age, skin atrophy, skin metabolism, underlying disease, and the route of administration.

These are not all the possible side effects of SERNIVO Spray.
What are the ingredients in SERNIVO Spray?

Active ingredients: *betamethasone dipropionate*

Inactive ingredients: butylated hydroxytoluene, cetostearyl alcohol, hydroxyethyl cellulose, methylparaben, mineral oil, oleyl alcohol, polyoxyl 20 cetostearyl ether, propylparaben, purified water, and sorbitan monostearate. SERNIVO Spray is co-packaged with a manual spray pump for installation by the pharmacist prior to dispensing to patients.

**8.3 Nursing Mothers**

Systemic administration of corticosteroids is inhuman milk and can suppress growth, including with prolonged corticosteroid production or sudden other corticosteroid withdrawal, as well as other corticosteroids. In rare cases, these effects may occur. Elderly patients can result in sufficient systemic absorption to produce detectable quantities in human milk. Because more drug is excreted in human milk, caution should be exercised when SERNOVO Spray is administered to nursing women.

**9. Package Quantity**

Each unit is co-packaged with a manual spray pump for installation by the pharmacist prior to dispensing to patients.

**10. CRITICAL PHARMACOLOGY**

10.1 Mechanism of Action

Contact to skin plays a role in local skin physiology, immune function, inflammation, and protein regulation; however, the precise mechanism of action of SERNIVO Spray is not yet understood.

10.2 Pharmacokinetics

Vaccination studies performed with SERNIVO Spray in healthy subjects indicate that it is in the middle range of potency as compared with other topical corticosteroids; however, individual skin response does not necessarily imply therapeutic equivalence.

The potential for HPA axis suppression by SERNIVO Spray was evaluated in a study involving 2 subjects with radiation-induced severe plaque psoriasis. SERNIVO Spray was applied twice daily for 15 days, in subjects with psoriasis baseline (cortisol) in the range of 5-10 mg/dL. The treatment resulted in a decrease of negative cortisol suppression at the end of treatment. The proportion of subjects demonstrating HPA axis suppression was 20% (5 of 26) in subjects treated with SERNIVO Spray for 15 days. In subjects treated with 15 days of treatment, cortisol suppression was not statistically significant compared with vehicle treatment. In the study, no adverse effects were detected except for 1 subject who had a small ACTH stimulation test.

**10.3 Pharmacodynamics**

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the skin barrier, and the use of occlusive dressings. Topical corticosteroids are absorbed through normal skin, but skin irritation and previous skin exposure to corticosteroids may increase percutaneous absorption. Plasma concentrations of betamethasone dipropionate, betamethasone-17-propionate, and betamethasone were measured at baseline, and before and after the last dose (1, 3, and 7 days) in the HPA axis suppression study in subjects with psoriasis. Compared with baseline, all subjects had increased ACTH stimulation tests at Day 7.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vehicle Spray (N/10)</td>
<td>Vehicle Spray (N/10)</td>
<td>Vehicle Spray (N/PY)</td>
</tr>
<tr>
<td>Treatment Success</td>
<td>21.5%</td>
<td>7.6%</td>
</tr>
<tr>
<td>Treatment Success at Day 29</td>
<td>42.7%</td>
<td>11.7%</td>
</tr>
</tbody>
</table>

**11. USES**

Spray pump for installation by the pharmacist prior to dispensing to patients.

**12. ANTICANCER THERAPY**

12.1 Mechanism of Action

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12.2 Pharmacokinetics

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**13. CLINICAL STUDIES**

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of betamethasone dipropionate.