HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SERNIVO® safely and effectively. See full prescribing information for SERNIVO® Spray.

SERNIVO® (betamethasone dipropionate) Spray, 0.05% for topical use

Indications and Usage
SERNIVO® Spray is indicated for the treatment of mild to moderate plaque psoriasis in patients 10 years of age and older.

Dosage and Administration
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.

Contraindications
SERNIVO® Spray is contraindicated for the treatment of mild to moderate plaque psoriasis in patients 10 years of age or older.

Warnings and Precautions
• Warnings:
  - Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression and Other Systemic Effects
  - Ocular Adverse Events
  - Hypertrophic Scarring
  - Visual Disturbance

• Precautions:
  - Pregnancy
  - Nursing Mothers
  - Children
  - Geriatric Use
  - Renal Impairment

Adverse Reactions
The most common adverse reaction (≥7%) in application site reactions, including pruritus, burning, and stinging. (4.2)

Patient Counseling Information
• Instructions about the right way to apply SERNIVO® Spray.

How should I use SERNIVO® Spray?
See the “Instructions for Use” for detailed information about the right way to apply SERNIVO® Spray.
• Use SERNIVO® Spray exactly as your doctor tells you to use it.
• Your doctor should tell you how much SERNIVO® Spray to use and where to apply it.
• Apply SERNIVO® Spray 2 times a day.
• Use SERNIVO® Spray just for the shortest amount of time needed to treat your plaque psoriasis. Tell your doctor if your skin condition is not getting better after 4 weeks of using SERNIVO® Spray. Do not use SERNIVO® Spray for longer than 4 weeks.
• Wash your hands after applying SERNIVO® Spray.
• Do not bandage, cover, or wrap the treated skin area.

What are the possible side effects of SERNIVO® Spray?
Some of the possible side effects of SERNIVO® Spray include itching, burning, stinging, pain, and thinning of skin (atrophy) at the treated site. These are all the possible side effects of SERNIVO® Spray.

Can I use SERNIVO® Spray on my face, scalp, or any other area of my body?
No. SERNIVO® Spray is for use on the skin only.

Is it safe for me to use SERNIVO® Spray if I am pregnant?
No. There are no adequate and well-controlled studies in pregnant women. SERNIVO® Spray should be avoided during pregnancy, if the potential benefit justifies the potential risk to the fetus.

Is it safe for me to use SERNIVO® Spray if I am breastfeeding?
It is not known whether SERNIVO® Spray is excreted in breast milk. The potential effect of SERNIVO® Spray on breastfed infants has not been evaluated.

Is it safe for me to use SERNIVO® Spray if I have any of the following medical conditions?
Your doctor should tell you how much SERNIVO® Spray to use and where to apply it.

How should I store SERNIVO® Spray?
Store SERNIVO® Spray at room temperature between 68°F to 77°F (20°C to 25°C).

How should I throw away SERNIVO® Spray?
Throw away (discard) any unused SERNIVO® Spray after 4 weeks.

Keep SERNIVO® Spray and all medicines out of the reach of children.

General information about the safe and effective use of SERNIVO® Spray.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SERNIVO® Spray for a condition for which it was not prescribed. Do not give SERNIVO® Spray to other people even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about SERNIVO® Spray that is written for health professionals.

Full Prescribing Information
SERNIVO® (ser-ne-vo) Spray, 0.05% (betamethasone dipropionate) USP (equivalent to 0.5 mg betamethasone) in a slightly viscous, slightly yellow, spray formulation for topical administration. (1)

PRESERVING INFORMATION
PRESCRIBING INFORMATION
SERNIVO®* (ser-ne-vo) (betamethasone dipropionate) Spray, 0.05%
What are the ingredients in SERNIVO® Spray?  

Active ingredients: betamethasone dipropionate  

Inactive ingredients: butylated hydroxytoluene, cetostearyl alcohol, hydroxyethyl cellulose, methylparaben, mineral oil, oleyl alcohol, polyoxy 20 cetostearyl ether, propylparaben, purified water, and sorbitan monostearate  

Manufactured by: DPT Laboratories, Ltd., San Antonio, TX 78215  

This Patient Information has been approved by the U.S. Food and Drug Administration  

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**Nursing Mothers**  

Systematically administered corticosteroids appear in human milk and can suppress growth, inhibits adrenal and pituitary function, may cause adverse effects on infants. The effects to infants of exogenous corticosteroids received in this manner is not known. However, it is known that systemic absorption of exogenous corticosteroids has resulted in adverse effects, including growth suppression of the infant.  

**Pediatric Use**  

Warnings 

In psoriasis, the risk of adrenal suppression with systemic and topical corticosteroids is dependent on the specific corticosteroid, route of administration, dosage, and duration of therapy. However, potential systemic absorption of corticosteroids, particularly high-potency corticosteroids, is not negligible. As a result, the adrenal suppression potential of corticosteroids may increase the risk of infection and possibly the risk of corticosteroid-induced Cushing’s syndrome.  

A potent topical corticosteroid, such as betamethasone dipropionate, may suppress the activity of the skin’s immune response to infection. Use of a potent topical corticosteroid should be limited to acute, symptomatic dermatoses.  

**8.3 Local Adverse Reactions**  

Local adverse reactions including skin atrophy have also been reported with use of high-potency topical corticosteroids.  

**8.4 Pediatric Use**  

Because of a higher ratio of skin surface area to body mass, pediatric patients are at greater risk of systemic toxicity, including HPA axis suppression and adrenal insufficiency, when treated with topical drugs.  

**12 CLINICAL PHARMACOLOGY**  

**12.1 Mechanism of Action**  

**12.2 Pharmacodynamics**  

**12.3 Pharmacokinetics**  

**14 CLINICAL STUDIES**  

**16 HOW SUPPLIED/STORAGE AND HANDLING**  

**17 PATIENT COUNSELING INFORMATION**  

**18.1 How Supplied/Storage**  

**18.3 Advice to the Patient**  

Inform patients of the following:  

- Do not use for longer than 4 consecutive weeks.  
- Avoid contact with the eyes.  
- Avoid use of SERNIVO Spray on the face, scalp, undereyes, groin or other intertriginous areas, unless directed by the physician.  
- Do not occlude the treatment area with bandage or other covering, unless directed by the physician.  
- Local reactions and skin atrophy are more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids.  
- Discontinue therapy when control is achieved, unless directed otherwise by the physician.  
- Do not use for longer than 4 consecutive weeks.  
- Avoid contact with the eyes.  
- Avoid use of SERNIVO Spray on the face, scalp, undereyes, groin or other intertriginous areas, unless directed by the physician.  
- Do not occlude the treatment area with bandages or other covering, unless directed by the physician.  
- Local reactions and skin atrophy are more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids.  

Manufactured by: DPT Laboratories, Ltd., San Antonio, TX 78215  

Distributed by: Perrigo Pharma, LLC, Perrigo House, Perrigo Park, Kalamazoo, MI 49001-3010.  

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