HIGHLIGHTS OF PRESCRIBING INFORMATION

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

SERNIVO® (betamethasone dipropionate) spray, for topical use
Initial U.S. Approval: 1975

---------- **RECENT MAJOR CHANGES** ----------
Dosage and Administration (2.1, 2.2) 3/2025

---------- **INDICATIONS AND USAGE** ----------
SERNIVO Spray is a corticosteroid indicated for the treatment of mild to moderate plaque psoriasis in adults. (1)

---------- **DOSAGE AND ADMINISTRATION** ----------
- Apply SERNIVO Spray topically to the affected skin areas twice daily. Rub in gently.
- If there are hard-to-reach areas of the body with affected skin, consider using the SERNIVO Spray with the telescopic device (if co-packaged); see full prescribing information for detailed instructions). (2.1)
- Use SERNIVO Spray for up to 4 weeks and not beyond. (2.1)
- Discontinue SERNIVO Spray treatment prior to 4 weeks of treatment, if control of plaque psoriasis is achieved. (2.1)
- Do not use if atrophy is present at the treatment site. (2.1)
- Do not bandage, cover, or wrap the treated skin area unless directed by a health care provider. (2.1)
- Avoid use on the face, scalp, axilla, groin, or other intertriginous areas. (2.1)
- Not for oral, ophthalmic, or intravaginal use. (2.1)
- See full prescribing information for preparation instructions for the pharmacist. (2.2)

---------- **DOSAGE FORMS AND STRENGTHS** ----------
Spray: 0.05% (equivalent to 0.5 mg betamethasone/g). SERNIVO Spray is supplied in a 120 mL bottle. (3)

---------- **CONTRAINDICATIONS** ----------
None (4)

---------- **WARNINGS AND PRECAUTIONS** ----------
- Endocrine System Adverse Reactions:
  - Topical corticosteroids, including SERNIVO Spray, can cause hypothalamic-pituitary-adrenal (HPA) suppression with the potential for glucocorticosteroid insufficiency. Consider periodic evaluations for HPA axis suppression. If HPA axis suppression is documented, gradually withdraw SERNIVO Spray and consider use of a less potent corticosteroid. (5.1)
  - Cushing's syndrome, hyperglycemia, and glucosuria may result from systemic absorption of topical corticosteroids. (5.1)
  - Pediatric patients may be more susceptible to systemic toxicity from use of topical corticosteroids. (5.1, 8.4)
- Ophthalmic Adverse Reactions: Topical corticosteroids, including SERNIVO Spray, may increase the risk of cataracts and glaucoma. If visual symptoms occur, consider referral to an ophthalmologist. (5.2)
- Allergic Contact Dermatitis: Topical corticosteroids, including SERNIVO Spray, can cause allergic contact dermatitis. If allergic contact dermatitis develops, gradually withdraw SERNIVO Spray and institute appropriate therapy. (5.3)

---------- **ADVERSE REACTIONS** ----------
The most common adverse reactions (≥1%) are application site reactions, including pruritus, burning and/or stinging, pain, and atrophy. (6.1)

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

See 17 for PATIENT COUNSELING INFORMATION

Revised: 09/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

***Sections or subsections omitted from the full prescribing information are not listed.**

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SERNIVO Spray is indicated for the treatment of mild to moderate plaque psoriasis in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage and Administration Instructions

SERNIVO Spray is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

Do not use if atrophy is present at the treatment site.

The recommended dosage and administration instructions are as follows:

- Prior to use, shake the SERNIVO Spray bottle.
- Apply SERNIVO Spray topically to the affected skin areas twice daily and rub in gently. Avoid use on the face, scalp, axilla, groin, or other intertriginous areas. Wash hands after applying SERNIVO Spray.
- SERNIVO Spray is available with or without a co-packaged telescopic device. If there are hard-to-reach areas of the body with affected skin, consider using the co-packaged telescopic device as follows:
  - Apply SERNIVO Spray to the affected skin areas, not to the silicone pad of the device.
  - Use the telescopic device to gently rub SERNIVO Spray into the hard-to-reach affected skin areas.
  - Cleanse the silicone pad after each use to remove any residual SERNIVO Spray.
- Refer to the Instructions for Use for more information regarding the use of the spray bottle and, if co-packaged, the telescopic device.
- Do not bandage, cover, or wrap the treated skin area unless directed by a health care provider.

Use SERNIVO Spray for up to 4 weeks of treatment. Do not use SERNIVO Spray for longer than 4 consecutive weeks *[see Warnings and Precautions (5.1)]*.

Discontinue SERNIVO Spray prior to 4 weeks of treatment if control of plaque psoriasis is achieved.

2.2 Preparation Instructions for the Pharmacist

Prior to dispensing SERNIVO Spray:

- Step 1. Remove the spray pump from the wrapper.
- Step 2. Remove and discard the cap from the bottle.
- Step 3. Keeping the bottle upright, insert the spray pump into the bottle and turn clockwise until it is closed tightly.
- Step 4. Dispense the bottle with the spray pump inserted.
- Step 5. Include the date dispensed in the space provided on the carton.

3 DOSAGE FORMS AND STRENGTHS

Spray: Each gram of SERNIVO Spray, 0.05% contains 0.643 mg betamethasone dipropionate USP (equivalent to 0.5 mg betamethasone) in a slightly thickened, white to off-white oil-in-water emulsion. SERNIVO spray is supplied in a 120 mL bottle.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Endocrine System Adverse Reactions

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

Topical corticosteroids, including SERNIVO Spray, can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during or after withdrawal of treatment. Factors that predispose a patient 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.

Because of the potential for systemic absorption, consider evaluating patients who are at risk of HPA axis suppression periodically for evidence of HPA axis suppression by using the adrenocorticotropic hormone (ACTH) stimulation test.

If HPA axis suppression is documented, gradually withdraw SERNIVO Spray and consider use of a less potent corticosteroid. If signs and symptoms of glucocorticosteroid insufficiency occur, supplemental systemic corticosteroids may be required.

Pediatric patients may be more susceptible to systemic toxicity due to their larger skin surface to body mass ratios. SERNIVO Spray is not approved for use in pediatric patients *[see Use in Specific Populations (8.4)]*.

In a trial of adult subjects with moderate to severe plaque psoriasis, abnormal ACTH stimulation test results suggestive of HPA suppression were identified in 5 out of 24 (20.8%) subjects after treatment with SERNIVO Spray twice daily for 15 days. No subject (0 out of 24) had abnormal ACTH stimulation test results after treatment with SERNIVO Spray twice daily for 29 days *[see Clinical Pharmacology (12.2)]*.

Systemic effects of topical corticosteroids, including SERNIVO Spray, may also manifest as Cushing's syndrome, hyperglycemia, and glucosuria.

Additional Considerations

Concomitant use of SERNIVO Spray with other corticosteroid-containing products may increase the total systemic corticosteroid exposure, and result in an increased risk for adverse reactions. Minimize the unwanted risks by using SERNIVO Spray as recommended *[see Dosage and Administration (2.1)]*.

5.2 Ophthalmic Adverse Reactions

Use of topical corticosteroids, including SERNIVO Spray, may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported postmarketing with the use of topical corticosteroid products, including betamethasone dipropionate *[see Adverse Reactions (6.2)]*.

Avoid contact of SERNIVO Spray with eyes. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

5.3 Allergic Contact Dermatitis

Use of topical corticosteroids, including SERNIVO Spray, can cause allergic contact dermatitis. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Corroborate such an observation with appropriate diagnostic patch testing. If allergic contact dermatitis develops, gradually withdraw SERNIVO Spray and institute appropriate therapy.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Endocrine System Adverse Reactions *[see Warnings and Precautions (5.1)]*
- Ophthalmic Adverse Reactions *[see Warnings and Precautions (5.2)]*
- Allergic Contact Dermatitis *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of SERNIVO Spray was evaluated in two randomized, multicenter, prospective vehicle-controlled clinical trials (Trials 1 and 2). In Trials 1 and 2 adult subjects with moderate plaque psoriasis of the body applied SERNIVO Spray or vehicle spray topically twice daily for 28 days. A total of 352 subjects applied SERNIVO Spray and 180 subjects applied vehicle spray *[see Clinical Studies (14)]*.

Adverse reactions that occurred in at least 1% of subjects treated with SERNIVO Spray for up to 28 days were application site reactions including pruritis, burning, pain, and atrophy.

Less common adverse reactions (with occurrence lower than 1% but higher than 0.1%) in subjects treated with SERNIVO Spray were application site reactions including telangiectasia, dermatitis, discoloration, folliculitis and skin rash, in addition to dysgeusia and hyperglycemia. These adverse reactions were not observed in subjects treated with vehicle.

6.2 Postmarketing Experience

Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been identified during post approval use of topical corticosteroids, including topical betamethasone products:

- *Local adverse reactions*: striae, irritation, dryness, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, hypertrichosis, and miliaria.
- *Hypersensitivity reactions*: contact dermatitis, pruritus, bullous dermatitis, and erythematous rash.
- *Endocrine disorders*: Cushing's syndrome, linear growth retardation, and delayed weight gain. *[see Use in Specific Populations (8.4)]*
- *Nervous system disorders*: intracranial hypertension. *[see Use in Specific Populations (8.4)]*
- *Ophthalmic adverse reactions*: cataracts, glaucoma, and increased intraocular pressure.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available data on SERNIVO Spray use in pregnant women to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Observational studies suggest an increased risk of low birthweight infants with the use of greater than 300 grams of potent or very potent topical corticosteroid during a pregnancy. Advise pregnant women that SERNIVO Spray may increase the risk of having a low birthweight infant and to use SERNIVO Spray on the smallest area of skin and for the shortest duration possible.

In animal reproduction studies, increased malformations, including umbilical hernias, cephalocele, and cleft palate, were observed after intramuscular administration of betamethasone dipropionate to pregnant rabbits during the period of organogenesis *(see Data)*. The available data do not allow the calculation of relevant comparisons between the systemic exposure of betamethasone dipropionate observed in animal studies to the systemic exposure that would be expected in humans after topical use of SERNIVO Spray.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population,

the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data: Administration of 0.05 mg/kg betamethasone dipropionate intramuscularly to pregnant rabbits during the period of organogenesis caused malformations. The abnormalities observed included umbilical hernias, cephalocele, and cleft palate.

8.2 Lactation

Risk Summary

There are no data regarding the presence of betamethasone dipropionate in human milk, the effects on the breastfed infant, or the effects on milk production after topical application of SERNIVO Spray to women who are breastfeeding.

It is possible that topical administration of betamethasone dipropionate could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SERNIVO Spray and any potential adverse effects on the breastfed infant from SERNIVO Spray or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use SERNIVO Spray on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply SERNIVO Spray directly to the nipple and areola to avoid direct infant exposure *[see Use in Specific Populations (8.4)]*.

8.4 Pediatric Use

The safety and effectiveness of SERNIVO Spray have not been established in pediatric patients.

Because of a higher ratio of skin surface area to body mass, pediatric patients are at greater risk than adults of systemic toxicity, including HPA axis suppression and adrenal insufficiency, when treated with topical corticosteroids *[see Warnings and Precautions (5.1)]*.

Systemic effects such as Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients, especially those with prolonged exposure to large doses of high potency topical corticosteroids.

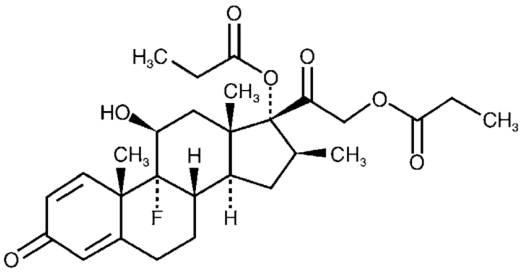
Local adverse reactions including skin atrophy have also been reported with use of topical corticosteroids in pediatric patients.

8.5 Geriatric Use

Clinical studies of SERNIVO Spray did not include sufficient numbers of subjects who were 65 years of age or older to determine whether they respond differently from younger adult subjects.

11 DESCRIPTION

The chemical name for betamethasone dipropionate is 9-fluoro-11(β), 17, 21-trihydroxy-16(β)-methylpregna-1,4-diene-3,20-dione-17,21-dipropionate. The empirical formula is $C_{28}H_{37}FO_7$ and the molecular weight is 504.6. The structural formula is shown below.



SERNIVO Spray contains 0.0643% betamethasone dipropionate (equivalent to 0.05% betamethasone), a synthetic, fluorinated corticosteroid for topical use.

Each gram of SERNIVO Spray contains 0.643 mg of betamethasone dipropionate USP (equivalent to 0.5 mg betamethasone) in a slightly thickened, white to off-white, oil-in-water, non-sterile emulsion with the following inactive ingredients: butylated hydroxytoluene, cetostearyl alcohol, hydroxyethyl cellulose, methylparaben, mineral oil, oleyl alcohol, polyoxyl 20 cetostearyl ether, propylparaben, purified water, and sorbitan monostearate.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the precise mechanism of action of SERNIVO Spray in the treatment of adults with mild to moderate plaque psoriasis is unknown.

12.2 Pharmacodynamics

Vasoconstrictor studies performed with SERNIVO Spray in healthy subjects indicate that it is in the mid-range of potency as compared with other topical corticosteroids; however, similar blanching scores do not necessarily imply therapeutic equivalence.

The potential for HPA axis suppression by SERNIVO Spray was evaluated in a study randomizing 52 adult subjects with moderate to severe plaque psoriasis (the safety and effectiveness of SERNIVO Spray has not been established in patients with severe plaque psoriasis *[see Indications and Usage (1)]*) to one of two SERNIVO Spray groups. In this study, SERNIVO Spray was applied twice daily for:

- 15 days in subjects with psoriasis involving a mean baseline body surface area (BSA) of 29% or
- 29 days in subjects with psoriasis that involved a mean baseline BSA of 27%.

In this study, 48 subjects were evaluated for HPA axis suppression at the end of treatment. In this study HPA axis suppression was defined as serum cortisol level ≤18 mcg/dL 30-minutes post-cosyntropin stimulation.

- The proportion of subjects that demonstrated HPA axis suppression was 21% (5 out of 24) in subjects treated with SERNIVO Spray for 15 days.
- No subjects (0 out of 24) treated with SERNIVO Spray for 29 days had HPA axis suppression.

In the 4 subjects with available follow-up values, all subjects had normal ACTH stimulation tests at follow-up.

12.3 Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids are absorbed through normal intact skin. Inflammation and/ or other disease processes in the skin may increase percutaneous absorption.

In the HPA axis suppression study in subjects with psoriasis *[see Clinical Pharmacology (12.2)],* plasma concentrations of betamethasone dipropionate, betamethasone-17-propionate, and betamethasone were measured at baseline, and before and 1, 3, and 6 hours after the last dose. In this study, the majority of subjects had no measurable plasma concentration (<5.00 pg/mL) of betamethasone dipropionate, while the metabolites, betamethasone-17-propionate and betamethasone, were detected in the majority of subjects (Table 2). There was high variability in the data but there was a trend toward higher systemic exposure at Day 15 and lower systemic exposure at Day 29.

Table 2: Mean (±SD) Maximum Plasma Concentrations (pg/mL) of Betamethasone Dipropionate Metabolites after 15 or 29 Days of Treatment with SERNIVO Spray

Analyte (pg/mL)	SERNIVO Spray Twice Daily (15 days)	SERNIVO Spray Twice Daily (29 days)
Betamethasone-17-propionate	120 ± 127	63.9 ± 52.6
Betamethasone	119 ± 176	57.6 ± 55.9

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

In a 90-day repeat-dose toxicity study in rats, topical administration of betamethasone dipropionate spray formulation at dose concentrations of 0.05% and 0.1% (providing dose levels up to 0.5 mg/kg/day in males and 0.25 mg/kg/day in females) resulted in a toxicity profile consistent with long-term exposure to corticosteroids including reduced body weight gain, adrenal atrophy, and histological changes in bone marrow, thymus and spleen indicative of severe immune suppression. A no observable adverse effect level (NOAEL) could not be determined in this study. Although the clinical relevance of the findings in animals to humans is not clear, sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk of carcinogenesis.

Betamethasone was negative in the bacterial mutagenicity assay (*Salmonella typhimurium* and *Escherichia coli*), and in the mammalian cell mutagenicity assay (CHO/HGPRT). It was positive in the in vitro human lymphocyte chromosome aberration assay, and equivocal in the in vivo mouse bone marrow micronucleus assay.
Studies in rabbits, mice, and rats using intramuscular doses up to 1, 33, and 2 mg/kg, respectively, resulted in dose-related increases in fetal resorptions in rabbits and mice.

14 CLINICAL STUDIES

The efficacy of SERNIVO Spray in in the treatment of moderate plaque psoriasis in adult subjects was evaluated in two multi-center, randomized, double-blind, vehicle-controlled clinical trials (Trials 1 and 2). In both trials, subjects applied SERNIVO Spray or vehicle spray topically to the affected areas twice daily for 28 days. Enrolled subjects had body surface area of psoriasis involvement between 10% to 20%, and an Investigator Global Assessment (IGA) score of 3 (moderate) on a 5-point IGA scale ranging from 0 (clear) to 4 (severe) in which the severity of erythema, scaling, and plaque elevation are assessed. Subjects ranged in age from 18 to 86 years, with a median age of 51 years. Overall, 62% of the subjects were male, 85% were White, 7% were Black, and 5% were Asian. For ethnicity, 30% of the subjects identified as Hispanic or Latino.

Efficacy was assessed as the proportion of subjects who were considered a treatment success (defined as having an IGA score of 0 or 1 [clear or almost clear] and at least a 2-grade reduction from baseline). Table 3 presents

the efficacy results at Day 15 and Day 29.

Table 3: Proportion of Adult Subjects with Moderate Plaque Psoriasis with Treatment Success[a] after 14 Days and 28 Days of Treatment in Trials 1 and 2

	Trial 1		Trial 2	
	SERNIVO Spray (N=182)	Vehicle Spray (N=95)	SERNIVO Spray (N=174)	Vehicle Spray (N=87)
Treatment Success at Day 15	21.5%	7.4%	19.0%	2.3%
Treatment Success at Day 29	42.7%	11.7%	34.5%	13.6%

[a] Treatment success is defined as an IGA of 0 or 1 (clear or almost clear) and at least a 2-grade reduction from baseline.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

SERNIVO Spray is a slightly thickened, white to off-white, non-sterile emulsion supplied in high density polyethylene bottles with a heat induction seal lined polypropylene cap. SERNIVO Spray is supplied as follows:

NDC	Volume	Co-packaged items
NDC 68040-714-28	120 mL	• Manual spray pump for preparation by the pharmacist prior to dispensing
NDC 68040-714-47	120 mL	• Manual spray pump for preparation by the pharmacist prior to dispensing • Telescopic device (Item 68040-75401)

Storage

- Store at controlled room temperature of 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
- Discard the bottle of SERNIVO Spray with manual spray pump and the telescopic device (if co-packaged) 28 days after the date of dispensing.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Administration Instructions

Inform patients of the following *[see Dosage and Administration (2.1)]*:

- Discontinue therapy when control of plaque psoriasis is achieved, unless directed otherwise by the healthcare provider.
- Do not use for longer than 4 consecutive weeks.
- If there are hard-to-reach areas of the body with affected skin, consider using the telescopic device (if co-packaged) to gently rub SERNIVO Spray into the affected skin areas. Cleanse the silicone pad of the telescopic device after each use.
- Wash hands after applying SERNIVO Spray.
- Avoid use of SERNIVO Spray on the face, scalp, underarms, 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.
- Discard the bottle of SERNIVO Spray with manual spray pump and the telescopic device (if co-packaged) 28

days after the date of dispensing.

Endocrine System Adverse Reactions
Instruct patients not to use other corticosteroids-containing products while using SERNIVO Spray without first consulting their healthcare provider *[see Warnings and Precautions (5.1)]*.

Ophthalmic Adverse Reactions
Advise patients to avoid contact with the eyes and in case of contact, wash eyes liberally with water. Instruct patients to tell their healthcare provider if they develop any visual symptoms *[see Warnings and Precautions (5.2)]*.

Lactation
Advise a woman to use SERNIVO Spray on the smallest area of skin and for the shortest duration possible while pregnant or breastfeeding. Advise breastfeeding women not to apply SERNIVO Spray directly to the nipple and areola to avoid direct infant exposure *[see Use in Specific Populations (8.2)]*.

Distributed by:
Primus Pharmaceuticals, Inc.,
Scottsdale, AZ 85253

SERNIVO is a registered trademark of Primus Pharmaceuticals, Inc.
www.primusrx.com

22519-02

PATIENT INFORMATION
SERNIVO® (ser-ne-vo)
(betamethasone dipropionate) spray
for topical use

Important: SERNIVO Spray is for use on the skin (topical use) only. Do not get SERNIVO Spray near or in your eyes, mouth, or vagina.

What is SERNIVO Spray?
SERNIVO Spray is a prescription corticosteroid medicine used to treat mild to moderate plaque psoriasis in adults.
It is not known if SERNIVO Spray is safe and effective in children. SERNIVO Spray is not recommended for use in children.

Before using SERNIVO Spray, tell your healthcare provider about all of your medical conditions, including if you:
- have thinning of the skin (atrophy) or broken skin at the treatment site
- have liver or adrenal gland problems, or high blood sugar (hyperglycemia)
- are pregnant or plan to become pregnant. It is not known if SERNIVO Spray will harm your unborn baby. SERNIVO Spray may increase your chance of having a low birthweight baby. If you use SERNIVO Spray during pregnancy, use it on the smallest area of skin and for the shortest time needed.
- are breastfeeding or plan to breastfeed. It is not known if SERNIVO Spray passes into breast milk. If you use SERNIVO Spray and breastfeed, use it on the smallest area of skin and for the shortest time needed. Do not apply SERNIVO Spray directly to the nipple and areola to avoid contact with your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take other corticosteroid medicines by mouth or use them on your skin. Do not take or use these products without talking to your healthcare provider first.

How should I use SERNIVO Spray?
See the Instructions for Use for detailed information on how to use SERNIVO Spray and, if included, the telescopic device.
- Use SERNIVO Spray exactly as your healthcare provider tells you to use it.
- Do not use SERNIVO Spray on skin that is thin (atrophied). Avoid use of SERNIVO Spray on your face, scalp, underarms (armpits), groin, or areas where your skin may touch or rub together.
- Apply SERNIVO Spray 2 times a day.
- SERNIVO Spray may come with a telescopic device to use as needed to help you rub SERNIVO Spray into affected skin areas that are hard to reach.
- Wash your hands after applying SERNIVO Spray.
- Do not bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to.
- Use SERNIVO Spray for the shortest amount of time needed. Tell your healthcare provider 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 in a row.

What are the possible side effects of SERNIVO Spray?
- **SERNIVO Spray can pass through your skin and cause problems with your endocrine system.** Too much SERNIVO Spray passing through your skin can cause:
  - your adrenal glands to not make enough or stop making hormones (adrenal insufficiency) during or after treatment with SERNIVO Spray. Your healthcare provider may do blood tests to check for adrenal gland problems.
  - **Cushing's syndrome**, a condition that happens when your body is exposed to too much of the hormone cortisol.
  - **High sugar in your blood (hyperglycemia) or in your urine (glucosuria).**
- **Vision problems**. SERNIVO Spray may increase your chance of developing vision problems such as cataracts and glaucoma. Tell your healthcare provider if you develop blurred vision or other vision problems during treatment. Rinse your eyes right away with water if you get SERNIVO Spray into your eyes.
- **Skin allergic reactions at the treated site**. Tell your healthcare provider if you get any skin reactions or skin infections during treatment.

The most common side effects of SERNIVO Spray include itching, burning, stinging, pain, and thinning of skin (atrophy) at the treated site.
These are not all of the possible side effects of SERNIVO Spray. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SERNIVO Spray?
- Store SERNIVO Spray at room temperature between 68˚F to 77˚F (20˚C to 25˚C).
- Throw away (discard) SERNIVO Spray and the telescopic device after 28 days (the date will be provided on the carton).

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 healthcare provider for information about SERNIVO Spray that is written for health professionals.

What are the ingredients in SERNIVO Spray?
Active ingredient: 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

Distributed by: Primus Pharmaceuticals, Inc. Scottsdale, AZ 85253

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised 09/2025

INSTRUCTIONS FOR USE
SERNIVO® (ser-ne-vo)
(betamethasone dipropionate) spray, for topical use

This Instructions for Use contains information on how to use SERNIVO Spray and, if included, the telescopic device. Read this Instructions for Use before you start SERNIVO Spray and each time you get a refill. There may be new information.

Important Information You Need to Know Before Using SERNIVO Spray:

- **SERNIVO Spray is for use on the skin (topical use) only.** Do not get SERNIVO Spray near or in your eyes, mouth, or vagina.
- Call your pharmacy if the pump is not attached to the bottle. Your pharmacist should assemble the bottle and pump before you receive SERNIVO Spray.

Parts of the SERNIVO Spray bottle. (See Figure A)

Figure A

Applying SERNIVO Spray:

Step 1: Shake the SERNIVO Spray bottle well. Remove the cap from the pump top.

Step 2: Hold the bottle in an upright position while pointing the opening of the pump top in the direction of the affected skin. To spray, push down on the pump top. Apply SERNIVO Spray to the affected area as instructed by your healthcare provider. **(See Figure B)**

Figure B

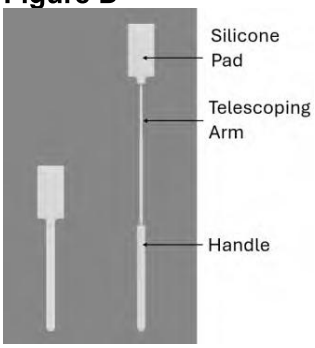
Step 3: Spray only enough SERNIVO Spray to cover the affected area, for example, the elbow **(See Figure C).** Rub in SERNIVO Spray gently. **If you cannot reach the affected area** to rub in the spray, see the optional **Step 4**.

Figure C

If needed, repeat Steps 2 and 3 to apply SERNIVO Spray to other affected skin areas as instructed by your healthcare provider.

Step 4 (if needed): SERNIVO Spray may come with a telescopic device if there are areas of skin that are hard to reach. You may use the telescopic device to gently rub the spray into the skin. The device has a silicone pad with a telescoping arm that moves “in” and “out” to help you reach the affected area. **(See Figure D)**

Figure D



The left side shows the telescopic device “in” (retracted).
The right side shows the telescopic device “out” (extended).

Do not apply SERNIVO Spray to the silicone pad. The telescopic device is only used to gently rub the spray into your skin.

- Extend the telescopic device by gently pulling the silicone pad while holding the handle.
- Gently rub the SERNIVO Spray into your skin using the silicone pad.
- Wash the silicone pad to remove any spray.
- Retract the telescopic device by gently pushing on the silicone pad.

Step 5: Wash your hands after you are finished applying SERNIVO Spray.

Step 6: After applying SERNIVO Spray, place the cap back onto the pump top. **(See Figure E)**

Figure E

Storing SERNIVO Spray:

- Store SERNIVO Spray at room temperature between 68˚F to 77˚F (20˚C to 25˚C).
- Throw away (discard) SERNIVO Spray and the telescopic device after 28 days (the date will be provided on the carton).

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

Distributed by:
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Scottsdale, AZ 85253

www.primusrx.com

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/s/

TATIANA OUSSOVA
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