

# Sernivo

(betamethasone dipropionate)



New Product  
Slideshow

MPR

# Introduction

- **Brand name:** Sernivo
- **Generic name:** Betamethasone dipropionate
- **Pharmacological class:** Corticosteroid
- **Strength and Formulation:** 0.05%; spray
- **Manufacturer:** Promius Pharma
- **How supplied:** Spray—60mL, 120mL
- **Legal Classification:** Rx

# SERNIVO



# Indications

- Mild-to-moderate **plaque psoriasis**

# Dosage & Administration

- $\geq 18$  yrs: apply to affected areas twice daily for up to max 4 weeks
- Discontinue when control is achieved
- Do not occlude

# Considerations for Special Populations

- **Pregnancy:** Category C
- **Nursing mothers:** Exercise caution
- **Pediatric:** <18yrs: not recommended
- **Geriatric:** Insufficient number studied

# Warnings/Precautions

- **Not for** oral, ophthalmic, or intravaginal use
- Systemic absorption increased by altered skin barrier, inflamed skin, prolonged use, application to large surface area, or use of occlusive dressings

# Warnings/Precautions

- **Discontinue** or reduce dose or potency if HPA axis suppression, Cushing's syndrome, hyperglycemia, glucosuria, or irritation occurs
- **Do not use** on face, axillae, or groin, or if atrophy is present at treatment site
- Allergic contact dermatitis
- Reevaluate periodically



# Adverse Reactions

- Pruritus
- Burning
- Stinging
- Pain
- Atrophy
- Telangiectasia
- Dermatitis
- Discoloration
- Folliculitis
- Skin rash
- HPA axis suppression (especially in children)

# 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 psoriasis is unknown

# Clinical Trials

- Two multicenter, randomized, double-blind, vehicle-controlled clinical trials were conducted in subjects aged 18 years and older with moderate plaque psoriasis
- Randomized subjects applied Sernivo Spray or vehicle spray to the affected area twice daily for 28 days

# Clinical Trials

- Efficacy was assessed as the proportion of subjects who were considered a treatment success
  - Defined as **IGA score 0** (clear) **or 1** (almost clear) and at least a 2-grade reduction from baseline

# Clinical Trials

- In Study 1 (n=277), treatment success at Day 15 was seen in **21.5%** of the Sernivo Spray group vs. **7.4%** in the vehicle spray group
- Treatment success at Day 29 was seen in **42.7%** of patients in the Sernivo Spray group vs. **11.7%** in the vehicle spray group

# Clinical Trials

- In Study 2 (n=261), treatment success at Day 15 was seen in **19.0%** of the Sernivo Spray group vs. **2.3%** of the vehicle spray group
- Treatment success at Day 29 was seen in **34.5%** of the Sernivo Spray group vs. **13.6%** of the vehicle spray group
- For more clinical trial data, see full labeling

# New Product Monograph

- For more information view the product monograph available at:

<http://www.empr.com/sernivo/drug/34591/>