NEW

Enstilar®
(calcipotriene and betamethasone dipropionate) Foam 0.005%/0.064%

Enstilar® Pharmacy Overview

What is Enstilar®?

- For adults with plaque psoriasis—Enstilar® is a once-daily topical treatment for plaque psoriasis in adults 18 years of age and older[1]
- Fixed-combination therapy—Enstilar® is a vitamin D analog and corticosteroid combination product[1]
- Sprays on as a foam—Enstilar® is delivered in a pressurized aluminum spray can with a continuous valve and actuator[1]

What data support the efficacy of Enstilar®?

- Over half of patients on Enstilar® achieved a 75% improvement of PASI score at Week 4[2]
- 53.3% of patients were "Clear" or "Almost Clear" by Week 4[1]
- Superior efficacy vs Taclonex® Ointment—4-week study demonstrates superior efficacy to Taclonex® Ointment[3]
- Rapid results with Enstilar® begin as early as Week 2, with 26.3% of patients achieving "Clear" or "Almost Clear" disease at Week 2[2]

What data support the safety of Enstilar®?

- Adverse reactions reported in <1% of subjects treated with Enstilar® in clinical trials included application site irritation, application site pruritus, folliculitis, skin hypopigmentation, hypercalcemia, urticaria, and exacerbation of psoriasis[1]

How is Enstilar® supplied?

Strength	Package Size	NDC Number
Enstilar® 60 g	1 carton containing One 60 g can	50222-302-60
Enstilar® 120 g	1 carton containing Two 60 g cans *Not for individual sale*	50222-302-66

There is no AB-rated equivalent for Enstilar®

Please see Important Safety Information on reverse and accompanying full Prescribing Information.

LEO®

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INDICATION AND USAGE

Enstilar® (calcipotriene and betamethasone dipropionate) Foam is indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.

Apply Enstilar® to affected areas once daily for up to 4 weeks. Patients should discontinue use when control is achieved. Instruct patients not to use more than 60 g every 4 days.

IMPORTANT SAFETY INFORMATION

For topical use only. Enstilar® is not for oral, ophthalmic, or intravaginal use. Instruct patients to avoid use on the face, groin, or axillae, or if atrophy is present at the treatment site, and not to use with occlusive dressings, unless directed by a physician.

The propellants in Enstilar® are flammable. Instruct patients to avoid fire, flame, or smoking during and immediately after using this product.

Hypercalcemia and hypercalciuria have been observed with use of Enstilar®. If hypercalcemia or hypercalciuria develop, patients should discontinue treatment until parameters of calcium metabolism have normalized.

Topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. Risk factors include use of high-potency topical corticosteroids, use over a large surface area or on areas under occlusion, prolonged use, altered skin barrier, liver failure, and use in pediatric patients. If HPA axis suppression is documented, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent steroid. Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria. Use of more than one corticosteroid-containing product at the same time may increase total systemic corticosteroid exposure.

Adverse reactions reported in <1% of subjects treated with Enstilar® in clinical trials included application site irritation, application site pruritus, folliculitis, skin hypopigmentation, hypercalcemia, urticaria, and exacerbation of psoriasis.

Patients who apply Enstilar® to exposed skin should avoid excessive exposure to either natural or artificial sunlight, including tanning booths, sun lamps, etc. You may wish to limit or avoid use of phototherapy in patients who use Enstilar®.

There are no adequate and well-controlled studies of Enstilar® in pregnant women. Enstilar® should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus. Because many drugs are excreted in human milk, caution should be exercised when Enstilar® is administered to a nursing woman. Do not use Enstilar® on the breast when nursing.

The safety and effectiveness of Enstilar® in pediatric patients have not been studied.

Visit **Enstilar.com** for more information.

Please see accompanying full Prescribing Information.

References: 1. Enstilar® [prescribing information]. Parsippany, NJ: LEO Pharma Inc.; October 2015. **2.** Data on File. Parsippany, NJ: LEO Pharma Inc.; 2015. **3.** Koo J, Tyring S, Werchler WP, et al. Superior efficacy of the fixed combination calcipotriene plus betamethasone dipropionate in an innovative aerosol foam versus ointment, in patients with psoriasis vulgaris. Supplement to *Dermatology News*. http://www.edermatologynews.com/fileadmin/content_pdf/san/supplement_pdf/LEO_Poster_summaries_2_17_15b.pdf. Accessed September 24, 2015.

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