

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ENSTILAR[®] Foam safely and effectively. See Full Prescribing Information for ENSTILAR[®] Foam.

ENSTILAR[®] (calcipotriene and betamethasone dipropionate) Foam, 0.005%/0.064% for topical use
Initial U.S. Approval: 2006

INDICATIONS AND USAGE

Enstilar[®] Foam is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older. (1)

DOSAGE AND ADMINISTRATION

- Shake before use. (2)
- Apply Enstilar[®] Foam to affected area(s) once daily for up to 4 weeks. Discontinue therapy when control is achieved. (2)
- Do not use more than 60 g every 4 days. (2)
- Do not use with occlusive dressings unless directed by a physician. (2)
- Not for oral, ophthalmic, or intravaginal use. (2)
- Avoid use on the face, groin, or axillae, or if skin atrophy is present at the treatment site. (2)

DOSAGE FORMS AND STRENGTHS

Foam, 0.005%/0.064%
Each gram of Enstilar[®] Foam contains 52.2 mcg calcipotriene hydrate (equivalent to 50 mcg of calcipotriene) and 0.643 mg of betamethasone dipropionate (equivalent to 0.5 mg of betamethasone). (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- The propellants in Enstilar[®] Foam are flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application. (5.1)
- Hypercalcemia and hypercalciuria have been observed with use of Enstilar[®] Foam. If hypercalcaemia or hypercalciuria develop, discontinue treatment until parameters of calcium metabolism have normalized. (5.2)
- Topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency during and after withdrawal of treatment. Risk factors include the 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. Modify use should HPA axis suppression develop. (5.3, 8.4)

ADVERSE REACTIONS

Adverse reactions reported in < 1% of subjects included application site irritation, application site pruritus, folliculitis, skin hypopigmentation, hypercalcemia, urticaria, and exacerbation of psoriasis. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact LEO Pharma Inc. at 1-877-494-4536 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA approved patient labeling.

Revised: 03/2016

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FULL PRESCRIBING INFORMATION

1 INDICATIONS 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.

2 DOSAGE AND ADMINISTRATION

Instruct patients to shake can prior to using Enstilar[®] Foam and to wash their hands after applying the product.

Apply Enstilar[®] Foam to affected areas once daily for up to 4 weeks. Rub in Enstilar[®] Foam gently. Discontinue use when control is achieved.

Instruct patients not to use more than 60 g every 4 days.

Enstilar[®] Foam should not be used with occlusive dressings unless directed by a physician. Enstilar[®] Foam is not for oral, ophthalmic, or intravaginal use.

Avoid use on the face, groin, or axillae, or if skin atrophy is present at the treatment site.

3 DOSAGE FORMS AND STRENGTHS

Foam, 0.005%/0.064%

Enstilar[®] Foam is a white to off-white opalescent liquid in a pressurized aluminum spray can with a continuous valve and actuator. At administration the product is a white to off-white foam after evaporation of the propellants. Each gram of Enstilar[®] Foam contains 52.2 mcg calcipotriene hydrate (equivalent to 50 mcg of calcipotriene) and 0.643 mg of betamethasone dipropionate (equivalent to 0.5 mg of betamethasone).

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Flammability

The propellants in Enstilar[®] Foam are flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application.

5.2 Hypercalcemia and Hypercalciuria

Hypercalcemia and hypercalciuria have been observed with use of Enstilar[®] Foam [see *Clinical Pharmacology (12.2)*]. If hypercalcaemia or hypercalciuria develop, discontinue treatment until parameters of calcium metabolism have normalized. The incidence of hypercalcemia and hypercalciuria following Enstilar[®] Foam treatment of more than 4 weeks has not been evaluated.

5.3 Effects on Endocrine System

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for clinical glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid. Factors that predispose a patient to HPA axis suppression include the use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. Evaluation for HPA axis suppression may be done by using the adrenocorticotrophic hormone (ACTH) stimulation test.

If HPA axis suppression is documented, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent corticosteroid.

Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria.

Pediatric patients may be more susceptible to systemic toxicity due to their larger skin surface to body mass ratios [see *Use in Specific Populations (8.3)*].

Use of more than one corticosteroid-containing product at the same time may increase total systemic corticosteroid exposure.

5.4 Allergic Contact Dermatitis

Allergic contact dermatitis has been observed with topical calcipotriene and topical corticosteroids. Allergic contact dermatitis to a topical corticosteroid is usually diagnosed by observing a failure to heal rather than a clinical exacerbation. Corroborate such an observation with appropriate diagnostic patch testing.

5.5 Risks of Ultraviolet Light Exposures

Patients who apply Enstilar[®] Foam to exposed skin should avoid excessive exposure to either natural or artificial sunlight, including tanning booths, sun lamps, etc.

Physicians may wish to limit or avoid use of phototherapy in patients who use Enstilar[®] Foam.

6 ADVERSE REACTIONS

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 practice.

The rates of adverse reactions given below were derived from three randomized, multicenter, prospective vehicle and/or active-controlled clinical trials in subjects with plaque psoriasis. Subjects applied study product once daily for 4 weeks, and the median weekly dose of Enstilar[®] Foam was 24.8 g.

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

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.

Postmarketing reports for local adverse reactions to topical steroids include atrophy, striae, telangiectasia, dryness, perioral dermatitis, secondary infection and miliaria.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Pregnant women were excluded from the clinical studies conducted with Enstilar[®] Foam. Enstilar[®] Foam should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus. Animal reproduction studies have not been conducted with Enstilar[®] Foam. Enstilar[®] Foam contains calcipotriene that has been shown to be fetotoxic and betamethasone dipropionate that has been shown to be teratogenic in animals when given systemically.

Teratogenicity studies with calcipotriene were performed by the oral route in rats and rabbits. In rabbits, increased maternal and fetal toxicity were noted at a dosage of 12 mcg/kg/day (144 mcg/m²/day); a dosage of 36 mcg/kg/day (432 mcg/m²/day) resulted in a significant increase in the incidence of incomplete ossification of the pubic bones and forelimb phalanges of fetuses. In a rat study, a dosage of 54 mcg/kg/day (324 mcg/m²/day) resulted in a significantly increased incidence of skeletal abnormalities (enlarged fontanelles and extra ribs). The enlarged fontanelles were most likely due to the effect of calcipotriene upon calcium metabolism. The estimated maternal and fetal no-adverse effect levels (NOAEL) in the rat (108 mcg/m²/day) and rabbit (48 mcg/m²/day) derived from oral studies are lower than the estimated maximum topical dose of calcipotriene in man (460 mcg/m²/day).

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels.

Betamethasone dipropionate has been shown to be teratogenic in mice and rabbits when given by the subcutaneous route at dosages of 156 mcg/kg/day (468 mcg/m²/day) and 2.5 mcg/kg/day (30 mcg/m²/day), respectively. Those dose levels are lower than the estimated

maximum topical dose in man (about 5,950 mcg/m²/day). The abnormalities observed included umbilical hernia, exencephaly and cleft palate.

Two oral peri- and post-natal development studies were conducted with rats:

Pregnant Wistar rats were dosed daily with calcipotriene at exposures of 0, 6, 18 or 54 mcg/kg/day from gestation day 15 through day 20 postpartum. No remarkable effects were observed on any parameter, including survival, behavior, body weight, litter parameters, or the ability to nurse or rear pups.

Betamethasone dipropionate was evaluated for effects when orally administered to pregnant rats from gestation day 6 through day 20 postpartum at dosages of 0, 100, 300, and 1000 mcg/kg/day. Mean maternal body weight was significantly reduced on gestation day 20 in animals dosed at 300 and 1000 mcg/kg/day. The mean duration of gestation was slightly, but statistically significantly, increased at 100, 300, and 1000 mcg/kg/day. The mean percentage of pups that survived to day 4 was reduced in relation to dosage. On lactation day 5, the percentage of pups with a reflex to right themselves when placed on their back was significantly reduced at 1000 mcg/kg/day. No effects on the ability of pups to learn were observed, and the ability of the offspring of treated rats to reproduce was not affected.

8.3 Nursing Mothers

Systemically administered corticosteroids appear in human milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects.

It is not known whether topically administered calcipotriene or corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk.

Because many drugs are excreted in human milk, caution should be exercised when Enstilar[®] Foam is administered to a nursing woman.

Instruct the patient not to use Enstilar[®] Foam on the breast when nursing.

8.4 Pediatric Use

Safety and effectiveness of the use of Enstilar[®] Foam in pediatric patients have not been studied. Because of a higher ratio of skin surface area to body mass, children under the age of 12 years are at particular risk of systemic adverse effects when they are treated with topical corticosteroids. They are, therefore, also at greater risk of HPA axis suppression and adrenal insufficiency with the use of topical corticosteroids. [see *Warnings and Precautions* (5.3)]

Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients treated with topical corticosteroids.

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

8.5 Geriatric Use

Of the total number of subjects in the controlled clinical studies of Enstilar[®] Foam in plaque psoriasis, 97 were 65 years or older, while 21 were 75 years or older.

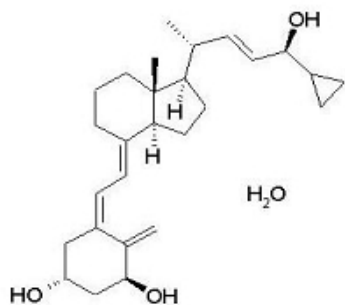
No overall differences in safety or effectiveness of Enstilar[®] Foam were observed between subjects in these subjects versus younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

11 DESCRIPTION

Enstilar[®] Foam contains calcipotriene hydrate and betamethasone dipropionate. It is intended for topical use only.

Calcipotriene hydrate is a synthetic vitamin D₃ analog.

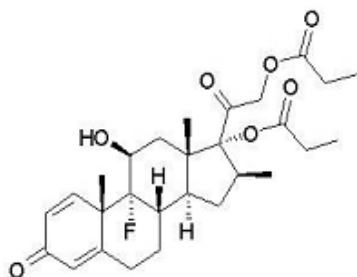
Chemically, calcipotriene hydrate is 9,10-secochola-5,7,10(19),22-tetraene-1,3,24-triol,24-cyclo-propyl-,monohydrate, (1 α ,3 β ,5 γ ,7 ϵ ,22 ϵ ,24 δ) with the empirical formula C₂₇H₄₀O₃·H₂O, a molecular weight of 430.6, and the following structural formula:



Calcipotriene hydrate is a white to almost white, crystalline compound.

Betamethasone dipropionate is a synthetic corticosteroid.

Betamethasone dipropionate has the chemical name *pregna-1,4-diene-3,20-dione-9-fluoro-11-hydroxy-16-methyl-17,21-bis(1-oxypropoxy)-(11 β ,16 β)*, with the empirical formula $C_{28}H_{37}FO_7$, a molecular weight of 504.6, and the following structural formula:



Betamethasone dipropionate is a white to almost white crystalline powder.

Enstilar[®] Foam is a white to off-white opalescent liquid in a pressurized aluminum spray can with a continuous valve and actuator. The propellants used in Enstilar[®] Foam are dimethyl ether and butane. At administration the product is a white to off-white foam after evaporation of the propellants. Each gram of Enstilar[®] Foam contains 52.2 mcg calcipotriene hydrate (equivalent to 50 mcg of calcipotriene) and 0.643 mg of betamethasone dipropionate (equivalent to 0.5 mg of betamethasone) in a base of white petrolatum, PPG-11 stearyl ether, mineral oil, all-rac-alpha-tocopherol, and butylhydroxytoluene.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Enstilar[®] Foam combines the pharmacological effects of calcipotriene hydrate as a synthetic vitamin D₃ analog and betamethasone dipropionate as a synthetic corticosteroid. However, while their pharmacologic and clinical effects are known, the exact mechanisms of their actions in plaque psoriasis are unknown.

12.2 Pharmacodynamics

Effects on Calcium Metabolism

Effects of once daily application of Enstilar[®] Foam for 4 weeks on calcium metabolism in adult subjects (N=564) with plaque psoriasis were examined in three randomized, multicenter, prospective vehicle- and/or active-controlled clinical trials. Following once daily application of Enstilar[®] Foam, elevated serum calcium levels outside the normal range were observed in 3 subjects. Elevated urinary calcium levels outside the normal range were observed in 17 subjects.

12.3 Pharmacokinetics

Absorption

The pharmacokinetics (PK) of Enstilar[®] Foam was investigated in adult subjects (N = 35) with moderate to severe plaque psoriasis with a mean body surface area involvement of 17.5% and mean scalp involvement of 50.2%. Plasma concentrations of calcipotriene

and betamethasone dipropionate and their main metabolites were measured after 4 weeks of once daily application of Enstilar[®] Foam. Following application of a mean $\pm$ SD total weekly dose of 61.8 ± 27.7 grams of Enstilar[®] Foam, calcipotriene was quantifiable in 1 of 35 (2.9%) subjects and its main metabolite, MC1080, in 3 of 35 (8.6%) subjects. For subjects with measurable concentrations, the maximal plasma concentrations (C_{max}) and area under the concentration curve until the last measured time point (AUC_{last}) for calcipotriene were 55.9 pg/mL and 82.5 pg*h/mL, respectively; and the mean $\pm$ SD C_{max} and AUC_{last} for MC1080 was 24.4 ± 1.9 pg/mL and 59.3 ± 5.4 pg*h/mL, respectively. Betamethasone dipropionate was quantifiable in 5 of 35 (14.3%) subjects and its main metabolite, betamethasone 17-propionate (B17P), was quantifiable in 27 of 35 (77.1%) subjects. The mean $\pm$ SD C_{max} and AUC_{last} for betamethasone dipropionate were 52.2 ± 19.7 pg/mL and 36.5 ± 27.4 pg*h/mL, respectively and for B17P were 147.9 ± 224.0 pg/mL and 683.6 ± 910.6 pg*h/mL, respectively. The clinical significance of these findings is unknown.

Metabolism

Calcipotriene:

Calcipotriene metabolism following systemic uptake is rapid and occurs in the liver. The primary metabolites of calcipotriene are less potent than the parent compound.

Calcipotriene is metabolized to MC1046 (the α,β -unsaturated ketone analog of calcipotriene), which is metabolized further to MC1080 (a saturated ketone analog). MC1080 is the main metabolite in plasma. MC1080 is slowly metabolized to calcitroic acid.

Betamethasone dipropionate:

Betamethasone dipropionate is metabolized to betamethasone 17-propionate (B17P) and betamethasone, including the 6 β -hydroxy derivatives of those compounds by hydrolysis. B17P is the primary metabolite.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

When calcipotriene was applied topically to mice for up to 24 months at dosages of 3, 10 and 30 mcg/kg/day (corresponding to 9, 30 and 90 mcg/m²/day), no significant changes in tumor incidence were observed when compared to control.

In a study in which albino hairless mice were exposed to both ultraviolet radiation (UVR) and topically applied calcipotriene, a reduction in the time required for UVR to induce the formation of skin tumors was observed (statistically significant in males only), suggesting that calcipotriene may enhance the effect of UVR to induce skin tumors.

A 104-week oral carcinogenicity study was conducted with calcipotriene in male and female rats at doses of 1, 5 and 15 mcg/kg/day (corresponding to dosages of approximately 6, 30, and 90 mcg/m²/day). Beginning week 71, the dosage for high-dose animals of both genders was reduced to 10 mcg/kg/day (corresponding to a dosage of approximately 60 mcg/m²/day). A treatment-related increase in benign C-cell adenomas was observed in the thyroid of females that received 15 mcg/kg/day. A treatment-related increase in benign pheochromocytomas was observed in the adrenal glands of males receiving 15 mcg/kg/day. No other statistically significant differences in tumor incidence were observed when compared to control. The relevance of these findings to patients is unknown.

When betamethasone dipropionate was applied topically to CD-1 mice for up to 24 months at dosages approximating 1.3, 4.2 and 8.5 mcg/kg/day in females, and 1.3, 4.2, and 12.9 mcg/kg/day in males (corresponding to dosages of up to approximately 26 mcg/m²/day and 39 mcg/m²/day, in females and males, respectively), no significant changes in tumor incidence were observed when compared to control.

When betamethasone dipropionate was administered via oral gavage to male and female Sprague Dawley rats for up to 24 months at dosages of 20, 60, and 200 mcg/kg/day (corresponding to dosages of approximately 120, 360, and 1200 mcg/m²/day), no significant changes in tumor incidence were observed when compared to control.

Calcipotriene did not elicit any genotoxic effects in the Ames mutagenicity assay, the mouse lymphoma TK locus assay, the human lymphocyte chromosome aberration test, or the mouse micronucleus test.

Betamethasone dipropionate did not elicit any genotoxic effects in the Ames mutagenicity assay, the mouse lymphoma TK locus assay, or in the rat micronucleus test.

Studies in rats with oral doses of up to 54 mcg/kg/day (324 mcg/m²/day) of calcipotriene indicated no impairment of fertility or general reproductive performance.

Studies in male rats at oral doses of up to 200 mcg/kg/day (1200 mcg/m²/day), and in female rats at oral doses of up to 1000 mcg/kg/day (6000 mcg/m²/day), of betamethasone dipropionate indicated no impairment of fertility.

14 CLINICAL STUDIES

Two multicenter, randomized, double-blind trials were conducted in subjects with plaque psoriasis. In Trial One, 302 subjects were randomized to 1 of 3 treatment groups: Enstilar[®] Foam, betamethasone dipropionate in the same vehicle, or calcipotriene hydrate in the same vehicle. In Trial Two, 426 subjects were randomized to 1 of 2 treatment groups: Enstilar[®] Foam or the vehicle alone. Baseline disease severity was graded using a 5-point Investigator's Global Assessment (IGA). At baseline subjects scored "Mild", "Moderate", or "Severe". The majority of subjects in both trials (76% and 75%) had disease of "Moderate" severity at baseline, 14% and 15% of subjects had disease of "Mild" severity at baseline and 10% of subjects had "Severe" disease at baseline in both trials. The extent of disease involvement assessed by mean body surface area was 7.1% (range 2 to 28%) and 7.5% (range 2 to 30%). In both trials, subjects were treated once daily for up to 4 weeks.

Efficacy was assessed with treatment success defined as the proportion of subjects at Week 4 who were "Clear" or "Almost Clear" according to the IGA. Subjects with "Mild" disease at baseline were required to be "Clear" to be considered a treatment success. Table 1 presents the efficacy results for these trials.

Table 1

Percentage of Subjects Achieving Treatment Success According to the Investigator's Global Assessment of Disease Severity*				
	Enstilar [®] Foam	Betamethasone dipropionate in vehicle	Calcipotriene in vehicle	Vehicle
Trial One	(N=100)	(N=101)	(N=101)	-
Week 4	45.0%	30.7%	14.9%	-
Trial Two	(N=323)	-	-	(N=103)
Week 4	53.3%	-	-	4.8%

*Subjects with "Mild" disease at baseline were required to be "Clear" to be considered a treatment success.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Enstilar[®] Foam is a white to off-white opalescent liquid in a pressurized aluminum spray can with a continuous valve and actuator. At administration the product is a white to off-white foam after evaporation of the propellants.

Enstilar[®] Foam is available in aluminum cans of:

- 1 x 60 g (NDC 50222-302-60)
- 2 x 60 g (NDC 50222-302-66)

16.2 Storage

- Store Enstilar[®] Foam at 20°- 25°C (68° -77°F); excursions permitted between 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].
- Contents under pressure. Do not puncture or incinerate. Do not expose to heat or store at temperatures above 120°F (49°C). Do not freeze.
- The product should be used within six months after it has been opened.

16.3 Handling

- Enstilar[®] Foam is flammable; avoid heat, flame or smoking when using this product.

17 PATIENT COUNSELING INFORMATION

[Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions For Use)]

Inform patients of the following:

- Instruct patients to shake before use.
- Instruct patients not to use more than 60 g every 4 days.
- Discontinue therapy when control is achieved unless directed otherwise by the physician.
- Avoid use of Enstilar[®] Foam on the face, underarms, groin or eyes. If this medicine gets on face or in mouth or eyes, wash area right away.
- Wash hands after application.
- Do not occlude the treatment area with a bandage or other covering unless directed by the physician. Instruct the patients not to use other products containing calcipotriene or a corticosteroid with Enstilar[®] Foam without first talking to the physician.
- Instruct patients who use Enstilar[®] Foam to avoid excessive exposure to either natural or artificial sunlight (including tanning booths, sun lamps, etc.). Physicians may wish to limit or avoid use of phototherapy in patients who use Enstilar[®] Foam.
- Enstilar[®] Foam is flammable; avoid heat, flame, or smoking when applying this medication.
- The foam can be sprayed holding the can in any orientation except horizontally.

Manufactured by:

Colep Laupheim GmbH & Co. KG

Fockestraße 12

88471 Laupheim

Germany (DE)

Distributed by:

LEO Pharma Inc.

1 Sylvan Way,

Parsippany, NJ 07054