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US MEDIA ONLY

LEO Pharma Inc. Announces FDA Approval of Enstilar[®] (calcipotriene and betamethasone dipropionate) Foam, 0.005%/0.064% for Plaque Psoriasis

The approval was based on pivotal clinical trial data at Week 4 that also showed patients using Enstilar[®] achieved efficacy as early as Week 2.

PARSIPPANY, New Jersey, October 19, 2015 -- LEO Pharma Inc., a wholly owned U.S. subsidiary of LEO Pharma A/S, announced today that Enstilar[®] has been approved by the U.S. Food and Drug Administration (FDA) for the topical treatment of plaque psoriasis in adults 18 years of age and older.¹

"The approval of Enstilar[®] may offer the appropriate plaque psoriasis patients a new treatment option in an elegant vehicle that provides rapid relief from symptoms," said Barbara J. Osborne, President and CEO of LEO Pharma Inc. "We are excited about the approval of Enstilar[®] as it represents another step in LEO Pharma's unwavering commitment to helping patients living with this chronic, often debilitating disease."

Enstilar[®] is a once-daily, alcohol free foam formulation in a pressurized spray can that allows application across large body areas of plaque psoriasis. In the pivotal Phase 3 clinical trial, over half of patients treated with Enstilar[®] were "Clear" or "Almost Clear" by Week 4 as assessed by the Investigator Global Assessment (IGA) score of disease severity.¹ Additionally, more than half of patients treated with Enstilar[®] achieved a 75% improvement in Psoriasis Area and Severity Index (PASI) score from baseline.²

Adverse reactions were reported in less than 1% of patients treated with Enstilar[®] and included application site irritation, application site pruritus, folliculitis, skin hypopigmentation, hypercalcemia, urticaria, and exacerbation of psoriasis.¹

"For the vast majority of plaque psoriasis patients using topical therapies as a first-line treatment option, having a therapy that can safely and effectively treat their symptoms is key," said Dr. Craig Leonardi, a Clinical Professor of Dermatology at St. Louis School of Medicine and the lead investigator of the clinical trial. "The approval of Enstilar[®] provides patients living with plaque psoriasis a new topical treatment option that was shown to be more effective than the ointment fixed combination and the individual components used alone."

For more information, visit Enstilar.com.

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.

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Hypercalcemia and hypercalciuria have been observed with use of Enstilar[®] Foam. 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.

About Psoriasis

Psoriasis is a chronic, inflammatory disease, which is frequently accompanied by multiple physical and/or psychological comorbidities, such as metabolic syndrome and psoriatic arthritis.³

Plaque psoriasis is estimated to affect about 2-4% of the population in the US.³ 80% of patients are affected by plaque psoriasis—the most common clinical form of psoriasis.³

Topical treatments are first-line therapies for the majority of patients since approximately 80% of the patients have mild or moderate plaque psoriasis.³

About LEO Pharma

Founded in 1908, LEO Pharma is an independent, research-based pharmaceutical company. LEO Pharma develops, manufactures and markets pharmaceutical drugs to dermatologic and thrombotic patients in more than 100 countries globally. The company has its own sales forces in 61 countries and employs around 4,800 people worldwide. LEO Pharma is headquartered in Denmark and is wholly owned by the LEO Foundation.

For more information visit www.leo-pharma.us.

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References

1. Enstilar[®] [prescribing information]. Parsippany, NJ: LEO Pharma Inc.; 2015.
2. Data on File. Parsippany, NJ: LEO Pharma Inc.; 2015.
3. Parisi R, et al. Global Epidemiology of Psoriasis: A Systematic Review of Incidence and Prevalence. The Society for Investigative Dermatology. *J Invest Dermatol* 2013;133(2):377-85.