

PRESCRIBING INFORMATION

Abbreviated Prescribing Information for Enstilar® (calcipotriol/betamethasone) 50 micrograms/g + 0.5 mg/g cutaneous foam

Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc or www.medicines.ie) before prescribing.

Indication: Topical treatment of psoriasis vulgaris in adults.

Active ingredients: 50 µg/g calcipotriol (as monohydrate) and 0.5 mg/g betamethasone (as dipropionate).

Dosage and administration: Apply by spraying onto affected area once daily. Recommended treatment period is 4 weeks. The daily maximum dose of Enstilar should not exceed 15 g, i.e. one 60 g can should last for at least 4 days. 15 g corresponds to the amount administered from the can if the actuator is fully depressed for approximately one minute. A two-second application delivers approximately 0.5 g. As a guide, 0.5 g of foam should cover an area of skin roughly corresponding to the surface area of an adult hand. If using other calcipotriol-containing medical products in addition to Enstilar, the total dose of all calcipotriol-containing products should not exceed 15 g per day. Total body surface area treated should not exceed 30%. Safety and efficacy in patients with severe renal insufficiency or severe hepatic disorders have not been evaluated. Safety and efficacy in children below 18 years have not been established. Shake the can for a few seconds before use. Apply by spraying, holding the can at least 3 cm from the skin, in any orientation except horizontally. Spray directly onto each affected skin area and rub in gently. Wash hands after use (unless Enstilar is used to treat the hands) to avoid accidentally spreading to other parts of the body. Avoid application under occlusive dressings since systemic absorption of corticosteroids increases. It is recommended not to take a shower or bath immediately after application.

Contraindications: Hypersensitivity to the active substances or any of the excipients. Erythrodermic and pustular psoriasis. Patients with known disorders of calcium metabolism. Viral (e.g. herpes or varicella) skin lesions, fungal or bacterial skin infections, parasitic infections, skin manifestations in relation to tuberculosis, perioral dermatitis, atrophic skin, striae atrophicae, fragility of skin veins, ichthyosis, acne vulgaris, acne rosacea, rosacea, ulcers and wounds.

Precautions and warnings: Adverse reactions found in connection with systemic corticosteroid treatment, e.g. adrenocortical suppression or impaired glycaemic control of diabetes mellitus, may occur also during topical corticosteroid treatment due to systemic absorption. Application under occlusive dressings should be avoided since it increases the systemic absorption of corticosteroids. Application on large areas of damaged skin, or on mucous membranes or in skin folds should be avoided since it increases the systemic absorption of corticosteroids. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for a referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Due to the content of calcipotriol, hypercalcaemia may occur. Serum calcium is normalised when treatment is discontinued. The risk of hypercalcaemia is minimal when the maximum daily dose of Enstilar (15 g) is not exceeded. Enstilar contains a potent group III-steroid and concurrent treatment with other steroids on the same treatment area must be avoided. Skin on the face and genitals are very sensitive to corticosteroids. Enstilar should not be used in these areas. Instruct the patient in the correct use of the product to avoid application and accidental transfer to the face, mouth and eyes.

Wash hands after each application to avoid accidental transfer to these areas. When lesions become secondarily infected, they should be treated with antimicrobiological therapy. However, if infection worsens, treatment with corticosteroids should be discontinued. When treating psoriasis with topical corticosteroids, there may be a risk of rebound effects when discontinuing treatment. Medical supervision should therefore continue in the post-treatment period. Long-term use of corticosteroids may increase the risk of local and systemic adverse reactions. Treatment should be discontinued in case of adverse reactions related to long-term use of corticosteroid. There is no experience with the use of Enstilar in guttate psoriasis. During Enstilar treatment, physicians are recommended to advise patients to limit or avoid excessive exposure to either natural or artificial sunlight. Topical calcipotriol should be used with UVR only if the physician and patient consider that the potential benefits outweigh the potential risks. Enstilar contains butylhydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Pregnancy and lactation: There are no adequate data from the use of Enstilar in pregnant women. Enstilar should only be used during pregnancy when the potential benefit justifies the potential risk. Caution should be exercised when prescribing Enstilar to women who breast-feed. The patient should be instructed not to use Enstilar on the breast when breast-feeding.

Side effects: There are no common adverse reactions based on the clinical studies. The most frequently reported adverse reactions are application site reactions. Uncommon ($\geq 1/1,000$ to $< 1/100$): Folliculitis, hypersensitivity, hypercalcaemia, skin hypopigmentation, rebound effect, application site pruritus, application site irritation. Not known (cannot be estimated from available data): Blurred vision, hair colour changes. *Calcipotriol:* Adverse reactions include application site reactions, pruritus, skin irritation, burning and stinging sensation, dry skin, erythema, rash, dermatitis, psoriasis aggravated, photosensitivity and hypersensitivity reactions, including very rare cases of angioedema and facial oedema. Systemic effects after topical use may appear very rarely causing hypercalcaemia or hypercalciuria. *Betamethasone:* Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation and colloid milia. When treating psoriasis with topical corticosteroids, there may be a risk of generalised pustular psoriasis. Systemic reactions due to topical use of corticosteroids are rare in adults; however, they can be severe. Adrenocortical suppression, cataract, infections, impaired glycaemic control of diabetes mellitus, and increase of intra-ocular pressure can occur, especially after long-term treatment. Systemic reactions occur more frequently when applied under occlusion (plastic, skin folds), when applied on large areas, and during long-term treatment.

Precautions for storage: Do not store above 30°C. Extremely flammable aerosol. Pressurised container. May burst if heated. Protect from sunlight. Do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source. Keep away from sparks/open flames. No smoking.

Legal category: POM.

Marketing authorisation number and holder: PL 05293/0008 (UK), PA 1025/5/1 (Ireland). LEO Pharma A/S, Ballerup, Denmark.

Basic NHS price (UK): £39.68/60 g, £79.36/2 x 60 g

Last revised: August 2018



Further information can be found in the Summary of Product Characteristics or from: LEO Pharma, Horizon, Honey Lane, Hurley, Berkshire SL6 6RJ, UK.
e-mail: medical-info.uk@leo-pharma.com/LEO Pharma, Cashel Road, Dublin 12, Ireland. e-mail: medical-info.ie@leo-pharma.com

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions:

For the **United Kingdom**, via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For **Ireland**, via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

Adverse events should also be reported to Drug Safety at LEO Pharma:

UK: +44 (0)1844 347333, e-mail: medical-info.uk@leo-pharma.com

Ireland: +353 1 4908924, e-mail: medical-info.ie@leo-pharma.com