

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

^{PR}ENSTILAR™

calcipotriol and betamethasone dipropionate aerosol foam

Read this carefully before you start using Enstilar™ and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Enstilar™.

What is Enstilar™ used for?

Enstilar™ is used to treat adults with a skin condition called psoriasis vulgaris.

How does Enstilar™ work?

Enstilar™ contains two medicines, calcipotriol and betamethasone, that work together to control psoriasis.

Psoriasis causes areas of inflamed skin where skin cells grow too fast. This creates red, scaly, thick patches (plaques) of skin.

Calcipotriol is a vitamin D-like substance that helps to bring the rate of skin cell growth back to normal. Betamethasone is a corticosteroid that works to reduce inflammation (redness, swelling and itching).

What are the ingredients in Enstilar™?

Medicinal ingredients: calcipotriol (as monohydrate) and betamethasone (as dipropionate)

Non-medicinal ingredients: all-rac- α -tocopherol, butylhydroxytoluene, liquid paraffin, polyoxypropylene-11-stearyl ether and white soft paraffin.

Propellants: butane, dimethyl ether

Enstilar™ comes in the following dosage forms:

Enstilar™ is a white to off-white flat, non-expanding aerosol foam containing 50 mcg/g calcipotriol (as monohydrate) and 0.5 mg/g betamethasone (as dipropionate). The product is alcohol-free and odourless.

Do not use Enstilar™:

- if you are allergic to any of the ingredients in Enstilar™ or the container (aluminium).
- if you have a condition that affects your calcium levels.
- if you have a skin infection caused by a virus, fungus, bacteria or parasite.
- if you have a skin condition related to tuberculosis.
- on areas with perioral dermatitis (rash around the mouth).

- on areas with thin skin, stretch marks or fragile veins.
- on areas with dry scaly skin caused by a condition called ichthyosis.
- on areas that have acne (pimples, redness), rosacea (red flushed facial skin), ulcers or wounds.
- if you have a type of psoriasis with severe inflammation called erythrodermic psoriasis, or a type of psoriasis with pus-filled blisters called pustular psoriasis.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use Enstilar™. Talk about any health conditions or problems you may have, including if you:

- have diabetes
- have a skin infection or if skin areas with psoriasis become infected
- use other medicines that contain corticosteroids or calcipotriol
- are pregnant or planning to get pregnant
- are breastfeeding
- are over 65 years old
- have problems with your kidneys or liver

Other warnings you should know about:

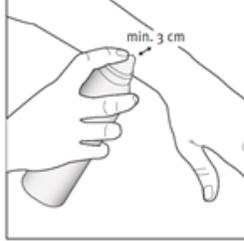
- Do not use Enstilar™ on your face, under the arms, in the groin area, in skin folds/creases or on areas of broken skin.
- Do not bandage, cover or wrap the treated skin area after applying Enstilar™.
- Limit or avoid prolonged exposure to natural and artificial sunlight (such as phototherapy, tanning beds and sun lamps) while using Enstilar™.
- Enstilar™ is not recommended for use in children.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Enstilar™:

The use of Enstilar™ with other medicines has not been studied. However, since medicines can interact with each other, tell your healthcare professional if you are using other medicines to treat your psoriasis. In particular, tell them if you are using medicines that contain corticosteroids.

How to use Enstilar™:

1. Shake the can before use.	
2. Hold the can at least 3 cm (1.2 inches) from the skin and spray. Use only on areas of your skin affected by psoriasis. If you accidentally get foam on your face, wipe it off right away.	
3. The foam can be sprayed by holding the can in any orientation except horizontally. Use in well-ventilated area and avoid inhalation	
4. Gently rub the foam into the affected skin areas.	
5. After applying the medication, put the cap back on the can. This will prevent accidental spraying when not in use.	
6. Leave the treated areas uncovered. Do not bandage, cover or wrap the skin. Enstilar™ should be left on the body until fully absorbed. Do not shower or take a bath immediately after application.	
7. Wash your hands after using Enstilar™ (unless you are using it to treat your hands). This will avoid accidentally spreading the foam to other parts of your body (especially the face, mouth and eyes).	

Recommended dose:

Apply once daily to affected areas for up to 4 weeks. Do not use more than 15g/day. One 60g can should last for at least 4 days. The maximum weekly dose of Enstilar™ (including other products containing calcipotriol) is 100g.

Overdose:

If you think you have used too much Enstilar™, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use Enstilar™, use it as soon as you remember. Next time, follow your regular application routine. Do not use Enstilar™ more than once a day.

What are possible side effects from using Enstilar™?

These are not all the possible side effects you may feel when using Enstilar™. If you experience any side effects not listed here, contact your healthcare professional.

Side effects from using Enstilar™ may include:

- itching, irritation or pain
- drying or reddening of the skin
- a burning or stinging sensation
- various types of skin rashes (dermatitis)
- acne
- small white spots
- thinning skin, stretch marks or surface veins
- red and swollen hair follicles
- changes in hair growth
- skin infection
- lightening of skin colour
- facial rash and swelling

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON Worsening of psoriasis: red, scaly, thick patches of skin		✓	
RARE Pustular psoriasis: chills, feeling unwell, fever, headache, joint pain, loss of appetite, nausea, red area with yellowish pimples			✓
Adrenal effects: fatigue, increased urination/thirst, problems controlling blood sugar levels, weakness, weight		✓	

loss			
VERY RARE Allergic reaction: dizziness, itching, rash, swelling, trouble breathing,			✓
Hypercalcaemia: constipation, depression, fatigue, increased urination/thirst, loss of appetite, mental confusion, nausea, vomiting			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.</p> <p>3 ways to report:</p> <ul style="list-style-type: none"> • Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php); • By calling 1-866-234-2345 (toll-free); • By completing a Consumer Side Effect Reporting Form and sending it by: <ul style="list-style-type: none"> - Fax to 1-866-678-6789 (toll-free), or - Mail to: Canada Vigilance Program Health Canada, Postal Locator 0701E Ottawa, ON K1A 0K9 <p>Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).</p> <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>

Storage:

Store Enstilar™ between 15° to 30°C.

After opening, the product should be stored at room temperature (15° to 30°C) and should be used within 6 months, and before expiry date. Keep out of reach and sight of children.

Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store at temperatures over 50°C. The product is very flammable. Do not use in presence of open flame or spark.

If you want more information about Enstilar™:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.leo-pharma.ca, or by calling 1-800-668-7234.

This leaflet was prepared by LEO Pharma Inc.

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