

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrENSTILAR[®]

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:

Aerosol foam; 50 mcg/g calcipotriol (as monohydrate) and 0.5 mg/g betamethasone (as dipropionate).

After spraying, the foam will not expand and will disintegrate gradually. The product is alcohol-free and has no odor.

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®.
- 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.


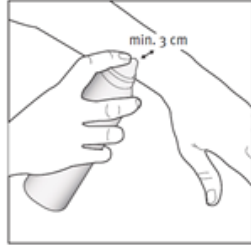


How to use Enstilar®:

Proper use:




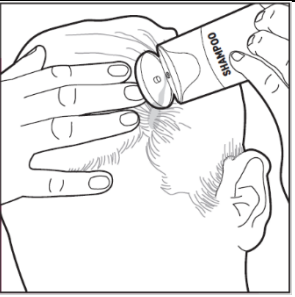
- Use only on areas of your skin affected by psoriasis. If you accidentally get foam on normal skin, wipe it off before it spreads too far.
- Wash or rinse off foam if applied to the following areas by accident:

- Eyes, mouth, genitals, or breasts (if you are breast feeding).
- Use Enstilar® in well-ventilated area and avoid breathing it in.
- Spraying Enstilar® for about 2 seconds is enough to cover an area of skin that is about the size of a patients' palm.
- After applying the medication, put the cap back on the can. This will prevent accidental spraying when not in use.
- Leave the treated areas uncovered. Do not bandage, cover or wrap the skin. Enstilar® should be left on the body until fully absorbed. For optimal effect, do not shower or take a bath immediately after applying the foam.
- After applying the foam, avoid contact with fabrics which are easily stained by grease (e.g. silk).

A. When Used on the Body:

<p>1. Shake the can for a few seconds before use.</p>	
<p>2. Hold the can at least 3 cm (1.2 inches) from the skin and spray.</p>	
<p>3. The foam can be sprayed by holding the can in any position except sideways.</p> <p>The product may feel cool when sprayed on the skin from the propellants evaporating.</p>	
<p>4. Gently rub the foam into the affected skin areas.</p>	
<p>5. Wash your hands well after using Enstilar® (unless you are using it to treat your hands). This will avoid spreading the foam to other parts of your body (especially the face, mouth and eyes) by accident.</p>	

B. When Used on the Scalp:

1. Comb the hair to remove any loose scales.	
2. Shake the can for a few seconds before use.	
3. Hold the can at least 3 cm away. Spray directly into the palm of your hand. The foam can be sprayed holding the can in any position except sideways. The product may feel cool when sprayed on the skin from the propellants evaporating.	
4. Scoop the foam onto your finger and apply it directly to the affected areas. Minimize applying into the hair to make it easier to wash it out. Gently rub the foam into the scalp.	
5. Wash your hands well after using Enstilar®. This will avoid spreading the foam to other parts of your body (especially the face, mouth and eyes) by accident.	
When you wash your hair, the following instructions might be useful:	
1. Apply a mild, nonmedicated shampoo to dry hair . Focus on the areas where the foam was applied. It is easier to remove Enstilar® when shampoo is applied to dry hair. Water dilutes the cleansing effect of the shampoo.	
2. Massage the shampoo into the dry hair/scalp . Leave the shampoo on the scalp for a couple of minutes before washing.	
3. Rinse thoroughly with water.	
4. Repeat normal shampooing if necessary.	

Usual dose:

There are two different dosage schedules for Enstilar®. Treatment dose is to treat your psoriasis and maintenance dose is to delay or reduce the risk of your psoriasis coming back after treatment.

Treatment dose:

- Apply once daily to affected areas for up to 4 weeks. Spraying Enstilar® for about 2 seconds is enough to cover an area of skin that is about the size of your palm. This is equal to about 0.5 g.
- **Do not** use more than 15g/day. 15 g corresponds to the amount of foam released when Enstilar® is sprayed for about one minute. One 60g can should last for at least 4 days. The maximum weekly dose of Enstilar® (including other products containing calcipotriol) is 100g.
- Stop using Enstilar® once you are satisfied with the results. If no improvement is seen after 4 weeks of treatment, go see your doctor. **Do not** use Enstilar® for more than 4 consecutive weeks, unless directed by your doctor.
- If your psoriasis comes back, you can restart Enstilar® as outlined above and contact your doctor as soon as possible to review your treatment.

Maintenance dose:

- Once your psoriasis has cleared or almost cleared, your doctor may recommend to continue using Enstilar® two times a week for up to one year. Between applications there should be 2 to 3 days without treatment (e.g. apply Monday and Thursday). **Do not** use more than 15g/day on application days.
- If symptoms reappear, use Enstilar® once daily as outlined above (treatment dose) and contact your doctor as soon as possible to review your treatment. If your psoriasis clears or almost clears, go back to using Enstilar® two times a week (maintenance dose).

Overdose:

If you think you, or a person you care for, have used too much Enstilar®, contact a 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 have when using Enstilar®. If you experience any side effects not listed here, tell your healthcare professional.

- itching, irritation or pain
- drying, reddening, or swelling 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 using 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 (high calcium levels in the blood): 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, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

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.
- 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.
- Keep out of reach and sight of children.

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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.leo-pharma.ca, or by calling 1-800-263-4218.

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Last Revised May 12, 2022