

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Enstilar®?

Enstilar® is a combination product that contains the active ingredients calcipotriol and betamethasone dipropionate. Enstilar® is a topical treatment for a skin condition called psoriasis.

For more information, see Section [1. Why am I using Enstilar®?](#) in the full CMI.

### 2. What should I know before I use Enstilar®?

Do not use if you have ever had an allergic reaction to Enstilar® or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Enstilar®?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Enstilar® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Enstilar®?

- Enstilar® is designed for direct application (spray on) to your skin where it is affected by psoriasis
- Enstilar® should be applied to dry skin on the affected areas of the body or scalp
- Your doctor will decide how much Enstilar® you need to use and for how long

More instructions can be found in Section [4. How do I use Enstilar®?](#) in the full CMI.

### 5. What should I know while using Enstilar®?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Enstilar®</li><li>• Protect the treated skin areas from sunlight and ultraviolet (UV) rays</li><li>• Inform your doctor and pharmacist that you are using Enstilar® if you are starting any new medicine</li><li>• Tell your doctor immediately if you become pregnant while using Enstilar®</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give your medicine to anyone else, even if they have the same condition as you</li><li>• Do not use more than the recommended daily or weekly dose</li><li>• Do not use other topical corticosteroids on areas treated with Enstilar®</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Enstilar® is not expected to affect your ability to drive or operate machinery</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Enstilar® in a cool dry place. Store below 25°C</li><li>• Enstilar® comes in a pressurised container and is extremely flammable. It may burst if heated. Protect from sunlight and do not expose to temperatures above 50°C</li></ul>

For more information, see Section [5. What should I know while using Enstilar®?](#) in the full CMI.

### 6. Are there any side effects?

Enstilar® may cause local skin reactions or irritation to the eyes and mucous membrane. Some common side effects include skin irritation, skin pain, rash, change in skin colour, increased skin sensitivity to light, change in control of diabetes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Enstilar®

## **Foam Spray**

**Active ingredient(s):** *Calcipotriol 50 microgram/g and Betamethasone 500 microgram/g present as dipropionate*

Calcipotriol (*Kal-sippo-try-all*) / Betamethasone (*Beet-ah-meth-ah sown*)

## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Enstilar®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Enstilar®.**

**Where to find information in this leaflet:**

- [1. Why am I using Enstilar®?](#)
- [2. What should I know before I use Enstilar®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Enstilar®?](#)
- [5. What should I know while using Enstilar®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using Enstilar®?**

**Enstilar® contains two active ingredients:**

- **Calcipotriol as monohydrate (related to Vitamin D);**
- **Betamethasone dipropionate (a corticosteroid)**

Enstilar® is a topical treatment for psoriasis. Psoriasis is a skin disorder in which skin cells are overactive. This causes redness, scaling and thickness of your skin.

The calcipotriol in Enstilar® treats the overactive skin cells. The betamethasone dipropionate relieves redness, swelling, itching and irritation of the skin.

Enstilar® is available only with a doctor's prescription.

## **2. What should I know before I use Enstilar®?**

### **Warnings**

**Do not use Enstilar® if:**

- you are allergic to calcipotriol, betamethasone dipropionate, or any of the ingredients listed at the end of this leaflet, or any other similar medicine such as topical corticosteroids.
- Always check the ingredients to make sure you can use this medicine.

**Do not use Enstilar® on skin affected by:**

- Viral, fungal, bacterial or parasitic skin infections
- Tuberculosis (TB)
- Perioral dermatitis (red rash around the mouth)
- Thin skin, easily damaged skin, stretch marks
- Ichthyosis (dry skin with fish like scales)
- Acne
- Rosacea
- Ulcers or broken skin

**Check with your doctor if you:**

- have high blood calcium levels
- have other types of psoriasis known as generalised pustular or erythrodermic exfoliative psoriasis (your doctor will identify these conditions for you)
- take any medicines for any other condition
- are suffering from any illness before using Enstilar®

Your doctor may do blood tests whilst you are using Enstilar® (or any other product containing calcipotriol, for example Daivobet® gel or ointment, Daivonex®). These tests check the levels of calcium in your blood and how well your kidneys are working ("renal function").

During treatment, you may be at risk of developing certain side effects. Some of the symptoms of an allergic reaction include shortness of breath, wheezing, or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or "hives" on the skin.

It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

**Do not use Enstilar® in children.** Safety and effectiveness of Enstilar® in those below 18 years of age has not been established.

## **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Enstilar®.

## 4. How do I use Enstilar®?

### How much to use

- Follow carefully all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.
- Enstilar® is for topical use (on the skin). Before use, read the patient information, even if you have used Enstilar® before. Enstilar® is designed for direct application (spray on) to your skin, where it is affected by psoriasis.
- **Important:** Do not use more than 15g in one day. 15g corresponds to the amount sprayed from the can when the actuator is fully pressed down for 1 minute.
- Do not use more than 100g in one week. One 60g can should last you at least 4 days.
- If you also use other calcipotriol containing products (e.g.: Daivobet® gel or ointment, Daivonex®) for your psoriasis, then the total amount of calcipotriol products must not exceed 15g per day or 100g per week.
- As a guide, a short 2 second spray of Enstilar® provides 0.5g of the medication and this amount should be sufficient to cover an area of skin roughly corresponding to the area of an adult hand.
- Follow the instructions provided and use Enstilar® until your doctor tells you to stop.

**NOTE:** If you use more than the recommended amount of Enstilar®, the levels of calcium in your blood may rise. This is known as “**hypercalcaemia**”.

Hypercalcaemia:

- is measured by a blood test
- may be harmful
- may mean that Enstilar® or any other product containing calcipotriol (eg., Daivobet® gel or ointment, Daivonex®) should not be used until the calcium level has become normal again.

Blood calcium levels will quickly normalize when your doctor discontinues Enstilar® treatment.

### When to use Enstilar®

- Apply Enstilar® **once a day** at the most convenient time for you, and try applying it about the same time of the day each day (for example, morning, afternoon, or evening)

### How long to use Enstilar®

- Each treatment course would normally last for up to four weeks.
- Your doctor may decide to stop treatment with Enstilar® or require you to use it twice weekly once your psoriasis has improved.
- If using Enstilar® twice weekly, it should be applied on two non-consecutive days (e.g. Wednesday and

Saturday) to areas previously affected by psoriasis.

There should be 2-3 days without Enstilar® treatment.

- If symptoms re-appear, you should use Enstilar® once daily as outlined above and contact your doctor to review your treatment.

### How to use Enstilar®

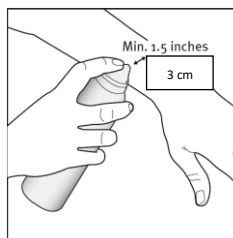
- Enstilar® should be applied to dry skin on the affected areas of the body or scalp.

#### For body psoriasis

1. Shake the can for a few seconds before use and remove the cap.



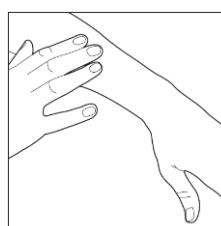
2. Apply the medication by holding the can at least 3cm (approximately 1.5 inches) from the skin and spray onto the affected area.



3. The foam can be sprayed by holding the can in any orientation except horizontally. Apply a layer of foam only to the psoriasis plaques. Spray directly onto each affected skin area and gently rub in. If you accidentally put some of the foam on normal skin, wipe it off as soon as possible.



4. Gently rub the foam into your affected skin areas. You will need to repeat steps 1 to 4 until all of the affected areas are covered.



5. After applying your medication, put the cap back on the can to prevent accidental pressing of the can when not in use.
6. Wash your hands well after using Enstilar® (unless you are using the foam to treat your hands). This will avoid accidentally spreading the foam to other parts of your body (especially face, mouth and eyes).



7. Take care not to get the foam spray in your eyes. If this happens, rinse your eyes with clean water and seek medical advice.
8. If you accidentally put some of the foam onto skin not affected by psoriasis, wipe it off as soon as possible.
9. Do not bandage, tightly cover or wrap the treated area.

For best results, leave on during the day or night. The treated area does not need to be covered. You may wear your usual clothes however avoid contact with fabric that is easily stained by grease (e.g. silk).

#### For scalp psoriasis

1. Comb the hair to remove any loose scales.
2. Shake the can for a few seconds before use and remove the cap.

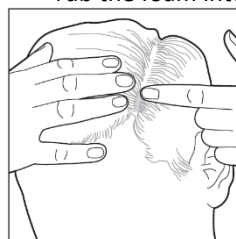


3. Hold the can at least 3 cm (1.5 inches) away. Spray directly into the palm of your hand. The foam can be sprayed holding the can in any orientation except horizontally.



4. Scoop the foam onto your finger and apply it directly to the affected areas of the scalp. Minimise applying

into the hair to make it easier to wash it out. Gently rub the foam into the scalp.



5. After applying your medication, put the cap back on the can to prevent accidental pressing of the can when not in use.
6. Wash your hands well after using Enstilar®. This will avoid accidentally spreading the foam to other parts of your body (especially the face, mouth and eyes).

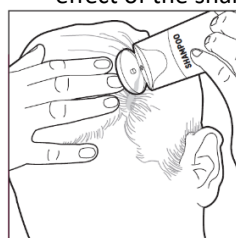


7. Take care not to get the foam in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
8. If you accidentally put some of the foam onto skin not affected by psoriasis, wipe it off as soon as possible.
9. Do not bandage, tightly cover or wrap the treated area.

For best results, do not wash your hair immediately after applying. Leave Enstilar® on during the day or night. The treated area does not need to be covered.

After applying to the scalp, the following instructions when washing your hair might be useful.

1. Apply a mild, non-medicated shampoo to the dry hair, focusing on the areas where the foam was applied. It is easier to remove Enstilar® when the shampoo is applied to dry hair as 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.

### If you forget to use Enstilar®

Enstilar® should be used regularly at the same time each day. If you miss your dose at the usual time, use it as soon as you remember, then continue as before. Do not use an increased dose of the foam to make up for the forgotten doses.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

### If you use too much Enstilar®

If you think that you have used too much Enstilar®, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Enstilar®?

### Things you should do

While you are using Enstilar®, protect the treated skin areas from sunlight and ultraviolet (UV) rays, for example, by wearing protective clothing. This is particularly important if your job or lifestyle means you spend time outdoors.

**Wash your hands thoroughly after applying Enstilar® on any parts of your body unless your hands are being treated.**

Thoroughly wash your hands prior to handling infants or children.

Enstilar® may cause a cool sensation on the skin when applied. If any skin irritation develops, **wash off the Enstilar®.**

**Call your doctor straight away if you:**

- If you are going to start any new medicine
- If you become pregnant while using Enstilar®

Remind any doctor, dentist or pharmacist you visit that you are using Enstilar®.

Keep all appointments with your doctor so that your progress can be checked.

### Things you should not do

- Do not use Enstilar®
  - on large areas of damaged skin;
  - in skin folds (eg., groin, underarm);
  - on the genitalia;

- inside the mouth, nose or in the eyes;
- on the face (an itchy red rash may develop);
- under occlusive dressings (such as a bandage)

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use more than the recommended daily or weekly dose
- Do not use other topical corticosteroids (eg., Advantan®, Diprosone®, Elocon®) on areas treated with Enstilar®.

### Driving or using machines

Enstilar® is not expected to affect your ability to drive or operate machinery

### Looking after your medicine

- Keep Enstilar® in the box until required.
- Store in a cool dry place, store below 25°C

Follow the instructions in the carton on how to take care of your medicine properly.

**CAUTION: Extremely flammable**

**Pressurised container: May burst if heated. Protect from sunlight and do not expose to temperatures above 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 and other ignition sources. Do not smoke while applying Enstilar®.**

Keep Enstilar® in the box to protect from light.

**Keep Enstilar® where young children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines

### Getting rid of any unwanted medicine

Ask your pharmacist what to do with any Enstilar® that is left over if

- your doctor tells you to stop using Enstilar®, or
- the can has been opened for more than 6 months, or
- the expiry date has passed.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Skin irritation including:</b> <ul style="list-style-type: none"><li>• Itching</li><li>• Redness</li></ul>	<b>Speak to your doctor if you have any of</b>

<ul style="list-style-type: none"> <li>• Dryness</li> <li>• Swelling</li> <li>• Peeling</li> </ul> <p><b>Other skin-related:</b></p> <ul style="list-style-type: none"> <li>• Skin pain (including burning)</li> <li>• Rash on your face or body</li> <li>• Change in skin colour</li> <li>• Skin becoming more sensitive to light</li> </ul>	<p><b>these less serious side effects and they worry you.</b></p>
---	---

## Serious side effects

Serious side effects	What to do
<p><b>Blood sugar-related:</b></p> <ul style="list-style-type: none"> <li>• Change in control of diabetes</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Enstilar® contains butylated hydroxytoluene.** This may cause local skin reactions (eg., contact dermatitis) or irritation to the eyes and mucous membranes.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Enstilar® contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>• Calcipotriol (50 microgram/g) [as monohydrate]</li> <li>• Betamethasone dipropionate (500 microgram/g)</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Liquid paraffin</li> <li>• Polyoxypropylene-11 stearyl ether</li> </ul>

	<ul style="list-style-type: none"> <li>• dl-alpha-tocopherol</li> <li>• White soft paraffin</li> <li>• Butylated hydroxytoluene (included as an antioxidant in polyoxypropylene-11 stearyl ether)</li> <li>• Propellants: butane and methyl ether</li> </ul>
--	--

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Enstilar® looks like

Enstilar® is in a pressurised can. After spraying, a white to off-white foam is formed on the skin. The foam is a non-expanding foam, which gradually collapses after spraying.

The Australian Registration Number is AUST R 263292.

This is not all the information available on Enstilar®. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

### Who distributes Enstilar®

Enstilar® is supplied in Australia by:

LEO Pharma Pty Ltd  
Brisbane, QLD Australia

Toll free no: 1800 991 778

Web: [www.leo-pharma.com.au](http://www.leo-pharma.com.au)

Enstilar, Daivobet, Daivonex, LEO and LEO/lion device are registered trademarks of LEO Pharma A/S.

This leaflet was prepared in March 2022.