

## **Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician's prescription only

# **ENSTILAR® CUTANEOUS FOAM**

### **Active ingredients:**

Betamethasone (as dipropionate) 0.5 mg/g

Calcipotriol (as monohydrate) 50 mcg/g

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read this entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

### **1. What is the medicine intended for?**

**Enstilar** is used on the skin to treat psoriasis vulgaris in adults.

### **Therapeutic group:**

Calcipotriol – a synthetic vitamin D derivative used for external treatment of psoriasis.

Betamethasone – a synthetic corticosteroid.

Psoriasis is caused by the skin cells being produced too quickly, which causes redness, scaling and thickening of the skin.

**Enstilar** contains Calcipotriol and Betamethasone. Calcipotriol helps control the rate of skin cell formation and Betamethasone reduces inflammation.

### **2. Before using the medicine:**

#### **Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredients (Calcipotriol, Betamethasone) or to any of the other ingredients this medicine contains (see section 6).
- You have problems with calcium levels in the blood (ask the doctor).
- You have certain types of psoriasis: erythrodermic or pustular psoriasis (ask the doctor if you are unsure).
- As **Enstilar** contains a strong steroid, do NOT use **Enstilar** on skin areas affected by:
  - skin infections caused by viruses (e.g. cold sores or chicken pox)
  - skin infections caused by a fungus (e.g. athlete's foot or ringworm)
  - skin infections caused by bacteria
  - skin infections caused by parasites (e.g. scabies)
  - tuberculosis
  - red rash around the mouth (perioral dermatitis)
  - thin skin, easily damaged veins, stretch marks
  - ichthyosis (dry skin with scales)
  - acne (pimples)
  - severe flushing or redness of the skin on the face (rosacea)
  - ulcers or wounds

### **Special warnings regarding the use of the medicine**

#### **• Before the treatment with Enstilar, tell the doctor if:**

- You suffer from diabetes (as your blood sugar level may be affected by the steroid).
- You are using other medicines that contain steroids, as you may get side effects.
- You have a certain type of psoriasis called guttate psoriasis.

#### **• During the treatment with Enstilar, tell the doctor if:**

- You have used this medicine for a long time and plan to stop (as there is a risk the psoriasis will get worse or flare up when steroids are stopped suddenly).
- The skin becomes infected, as you may need to stop treatment.
- The calcium level in the blood changes (see section 4 for further information).
- You experience blurred vision or other visual disturbances.
- Avoid use under bandages or dressings as this increases the absorption of the steroid.
- Avoid using more than 15 grams per day. This means that one 60 grams can of **Enstilar** should last for at least 4 days. 15 grams is dispensed if you fully depress the actuator for approximately 1 minute. Spraying for 2 seconds provides approximately 0.5 grams of **Enstilar**. As a guide, 0.5 grams of foam should cover an area of skin roughly corresponding to the surface area of an adult hand.
- Avoid use on more than 30% of the body.
- Avoid use on large areas of damaged skin, on mucous membranes or in skin folds (groin, armpits, under breasts) as this increases the absorption of the steroid.
- Avoid use on the face or genitals (sexual organs) as these areas are very sensitive to steroids.
- The medicinal product is extremely flammable. See section 5 "How to store the medicine?" for further information.

Do not smoke or get near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

### **Children and adolescents**

This medicine is not intended for the use in children below 18 years of age.

### **Drug interactions**

**If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before using this medicine. If the doctor has agreed that you can breastfeed, take care and do not apply **Enstilar** to the breast area (see "How to use the medicine?" in section 3).

### **Driving and using machines**

This medicine should not have any effect on your ability to drive or use machines.

### **Important information about some of the ingredients of the medicine**

**Enstilar** contains butylhydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes (see section 3).

## **3. How to use the medicine?**

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The medicine is intended for cutaneous use (on the skin).

Before use, read the patient package leaflet, even if you have used **Enstilar** before.

**Enstilar** is designed for direct application (spray-on) to the skin affected by psoriasis.

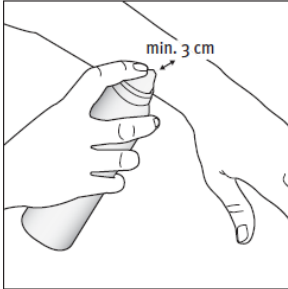
### **Instructions for use**

#### When used on the body

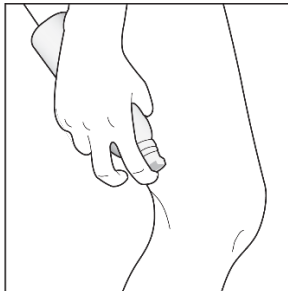
1. Shake the can for a few seconds before use.



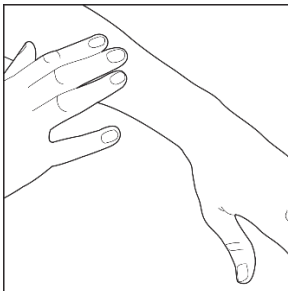
2. Hold the can at least 3 cm from the skin and spray directly onto each affected area.



3. The foam can be sprayed holding the can in any orientation except horizontally.



4. Gently rub the foam into each affected area.



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

In order to achieve optimal results, it is recommended that the body is not washed immediately after application of **Enstilar**.

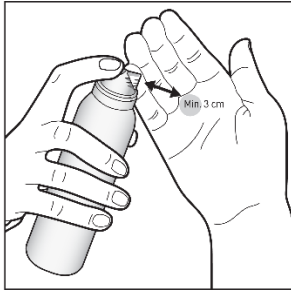
Let the foam remain on the skin during the night or during the day.

#### 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 from the skin and spray directly into the palm of the hand. The foam can be sprayed holding the can in any orientation except horizontally.



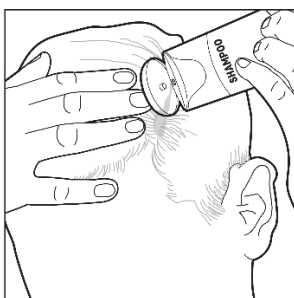
4. Scoop the foam onto the finger and apply it directly to the affected areas. Minimize applying into the hair to make it easier to wash it out. Gently rub the foam into the scalp. After applying the foam, put the cap on the can to prevent accidental spraying when the can is not in use.



5. Wash the hands well after using **Enstilar**, to avoid accidentally spreading the foam to other parts of the body (especially the face, mouth and eyes). In order to achieve optimal results, it is recommended that the hair is not washed immediately after application of **Enstilar**. Let the foam remain on the scalp during the night or during the day.

**When washing the hair, the following instructions may be useful:**

1. Apply a mild, non-medicated shampoo to **dry hair**, focusing on the areas where the foam was applied. It is easier to remove **Enstilar** when 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 the hair thoroughly with water.
4. Repeat normal shampooing if necessary.

Further information for instructions for use:

- Use only on skin areas affected by psoriasis and do not use on skin which is not affected by psoriasis.
- Wash well with water, if by accident, you have applied foam to your eyes, mouth, sexual organs or breasts (if you are breastfeeding).
- Do not worry if some of the foam accidentally gets on normal skin near the psoriasis but wipe it off if it spreads beyond the treated area.
- Do not bandage, tightly cover or wrap the treated skin area.
- In order to achieve optimal results, it is recommended not to take a shower or bath immediately after applying the foam.
- After applying the foam, avoid contact with textiles which are easily stained by grease (e.g. silk).

#### Duration of treatment

- The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is: apply once a day.
- **Do not exceed the recommended dose.** Do not swallow! For external use only.
- It may be more convenient to use in the evening.
- The normal treatment period is 4 weeks, but the doctor may decide on a different treatment period.

#### **If you used more Enstilar than you should**

**Important:** One 60 grams can of **Enstilar** should last for at least 4 days (see section 2 "Special warnings regarding the use of the medicine"). If you use other Calcipotriol containing medicines, the total amount of Calcipotriol medicines, including **Enstilar**, must not exceed 15 grams per day.

Contact the doctor if you have used more than the recommended dose.

Excessive use may cause problems with calcium levels in the blood, which usually return to normal when treatment is discontinued.

Excessive prolonged use can also cause the adrenal glands to stop working properly (the adrenal glands are found near the kidneys and produce hormones). See section 4 for further information.

If a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

#### **If you forget to use the medicine**

If you forgot to use the foam at the designated time, do not take a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by the doctor.

#### **If you stop using the medicine**

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the doctor. It may be necessary to stop using this medicine gradually, especially if you have used it for a long time.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have any further questions on the use of this medicine, consult the doctor or pharmacist.**

#### **4. Side effects**

Like any medicine, the use of **Enstilar** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Enstilar** contains Betamethasone (a strong steroid) and Calcipotriol. You may therefore experience the following side effects. These side effects are more likely to happen if **Enstilar** is used for a long time, if used under bandages or in skin folds (e.g., groin, armpits or under breasts), or if used on large skin areas.

**Refer to a doctor immediately with the occurrence of the following side effects:**

- Allergic reactions with swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and trouble breathing may also occur.
- Increase in calcium levels in the blood or urine which causes symptoms. Signs are frequent urination, constipation, muscle weakness and confusion. When the treatment is stopped, the calcium levels return to normal.
- Your adrenal glands may stop working properly. Signs are tiredness, depression, anxiety.
- Cloudy vision, difficulty seeing at night, sensitivity to light (this could be a sign of cataract).
- Eye pain, red eye, decreased vision or cloudy vision (this could be a sign of increased pressure inside the eye).
- Infections (because your immune system is weakened).
- Pustular psoriasis (a red area of psoriasis with yellowish pustules [pimples]).
- You may experience fluctuations in blood sugar levels.

**The following side effects have been reported for Enstilar:**

**Uncommon side effects** (effects that occur in 1-10 users out of 1,000):

- Allergic reaction. Symptoms may include skin rash and swelling of the skin, face or mouth
- Worsening or flare up of the psoriasis after treatment has stopped
- A rise in calcium levels in the blood
- Skin irritation which might include itching, pain, burning and stinging and/or redness of the skin
- Redness, pain or swelling of the hair roots of the skin (folliculitis)
- Loss of skin color (depigmentation)

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):

- Blurred vision
- Redness of the skin where the product is applied

**Less serious side effects known to be caused by the active ingredient Calcipotriol or Betamethasone include:**

- Thinning of the skin
- Stretch marks
- Blood vessels under the skin may become more noticeable
- Changes in hair growth
- Red rash around the mouth (perioral dermatitis)
- Worsening of psoriasis
- Sensitivity of the skin to light resulting in a rash
- Itchy skin rash (eczema)
- White or grey hair can transiently change to a yellowish color at the application site when used on the scalp

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

**Caution:** 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 and other ignition sources. No smoking near the can.

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C. Can be used up to 6 months after first opening.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Additional information**

### **In addition to the active ingredients, the medicine also contains:**

White soft paraffin, polyoxypropylene stearyl ether, liquid paraffin, butylhydroxytoluene (E321), all-rac- $\alpha$ -tocopherol, butane, dimethyl ether

### **What the medicine looks like and what the package contains:**

**Enstilar** is a foam used on the skin. After spraying, a white to off-white foam is formed.

Can with a continuous valve and actuator. The can contains 60 grams of foam (not including the amount of propellants).

Approved package sizes: 60 gram and 2 x 60 gram in a package.

Not all package sizes may be marketed.

**Manufacturer and address:** LEO Pharma A/S, Ballerup, Denmark

Revised in November 2022 according to MOH guidelines

**Drug registration number at the national drug registry of the Ministry of Health:**

163-91-35848

**Registration holder:** Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel