Enstilar® 50 micrograms/g + 0.5 mg/g cutaneous foam
calcipotriol/betamethasone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor, pharmacist or nurse.
• If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

General information
Enstilar contains calcipotriol and betamethasone. Calcipotriol helps to bring the rate of skin cell growth back to normal and betamethasone helps to reduce the inflammation caused by psoriasis.

1. What Enstilar® is and what it is used for
Enstilar is used on the skin to treat psoriasis vulgaris in adults. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling and thickness of your skin.

2. What you need to know before you use Enstilar®
Do not use Enstilar:
• if you are allergic to calcipotriol, betamethasone or any of the other ingredients of this medicine (listed in section 6).
• if you have problems with calcium levels in your blood (ask your doctor).
• if you have certain types of psoriasis called: erythrodermic psoriasis or pustular psoriasis (ask your 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 chickenpox)
• skin infections caused by fungi (e.g. athlete’s foot and ringworm)
• skin infections caused by bacteria
• skin infections caused by parasites (e.g. scabies)
• pemphigus vulgaris (red rash all over the mouth)
• thin skin, easily damaged veins, stretch marks
• erythema nodosum (red skin with hard lumps)
• acne (pimples)
• rosacea (severe flushing or redness of the skin on the face)
• ulcers and wounds.

3. How to use Enstilar®
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Enstilar is for cutaneous use (on the skin). Before use, read the patient information, even if you have used Enstilar before.

4. Gently rub the foam into each affected skin area.

5. After applying the foam, put the cap back on the can to prevent accidental spraying 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 the face, mouth and eyes).

Further information for proper use:
• use only on your psoriasis and do not use on skin which does not have psoriasis
• wash or rinse well if, by accident, you have applied foam to your eyes, mouth, sexual organs or breasts if you are not breast-feeding.
• do not worry if some foam accidentally gets on normal skin near your psoriasis, but wipe it off if it spreads too far.
• do not bandage, tightly cover or wrap the treated skin area.
• in order to achieve optimal effect, it is recommended not to use a shower or bath immediately after spraying the foam.
• after applying the foam, avoid contact with textiles which are easily stained by grease (e.g. silk).

Duration of treatment
• apply the foam once daily. It may be more convenient to use the foam in the evening.
• the normal treatment period is 4 weeks but your doctor may decide on a different treatment period.

If you use more Enstilar than you should
Important: One 60 g can of Enstilar should last for at least 4 days (see section 2 “Special precautions”). If you use other calcipotriol containing medicines, the total amount of calcipotriol medicines, including Enstilar, must not exceed 15 grams per day. Contact your doctor if you have used more than the recommended dose.

Excessive use of Enstilar may cause a problem with calcium in your blood, which usually returns to normal when treatment is discontinued.

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

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 sources. No smoking near the can.

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date, which is stated on this carton and can after EXP. The expiry date refers to the last day of that month.

The can should be discarded 6 months after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Enstilar contains

The active substances are: Calcipotriol and betamethasone. One gram of cutaneous foam contains 50 micrograms of calcipotriol (as monohydrate) and 0.5 mg of betamethasone (as dipropionate).

The excipients are:
- Liquid paraffin
- Polyoxypropylene stearyl ether
- All-rac-α-tocopherol
- White soft paraffin
- Butylhydroxytoluene (E321)
- Butane
- Dimethyl ether.

What Enstilar looks like and contents of the pack

Enstilar is a cutaneous foam. After spraying, a white to off-white foam is formed. Aluminium can with a polyamide-imide inner lacquer, equipped with a continuous valve and actuator. The can contains 60 g of foam, not including the amount of propellants.

Pack sizes: 60 g, 2 x 60 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:
- Enstilar: Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, United Kingdom
- Enstilar: Belgium, Luxembourg, Romania, Slovenia

This leaflet was last revised in March 2018.

Detailed information on this medicine is available on the website of the Health Products Regulatory Authority, www.hpra.ie and Medicines and Healthcare products Regulatory Agency, www.mhra.gov.uk