Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Enstilar 50 micrograms/g + 0.5 mg/g cutaneous foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of cutaneous foam contains 50 micrograms of calcipotriol (as monohydrate) and 0.5 mg of betamethasone (as dipropionate).

Excipient with known effect
Butylhydroxytoluene (E321)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous foam.

Product imported from Spain:
After spraying, a white to off-white foam is formed.
The foam has the appearance of a non-expanding foam that gradually collapses after spraying.

4 CLINICAL PARTICULARS

As per PA1025/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1025/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Polyoxypropylene stearyl ether
All-rac-α-tocopherol
White soft paraffin
Butylhydroxytoluene (E321)
Butane
Dimethyl ether

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product is the date shown on the can and outer carton of the product as marketed in the country of origin.

After first opening: 6 months.

6.4 Special precautions for storage

Do not store above 30°C.
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.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/265/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th September 2026

10 DATE OF REVISION OF THE TEXT