

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

DiproSalic 0.05% w/w + 2% w/w scalp application

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

0.05% w/w Betamethasone (as dipropionate)

2.00% w/w Salicylic Acid.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution

Product imported from Portugal:

A colourless, translucent viscous cutaneous solution.

4 CLINICAL PARTICULARS

As per PA23198/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate

Hypromellose (Methocel E 4M Premium EP)

Sodium hydroxide

Isopropyl alcohol

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.

The shelf life after opening the bottle is 6 weeks.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Low Density Polyethylene (LDPE) counter-drip bottle. Each bottle contains 100 ml of product."

6.6 Special precautions for disposal

No special 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

PPA1463/206/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2023

10 DATE OF REVISION OF THE TEXT