

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 the 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 PA1286/029/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/029/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

hydroxypropyl methylcellulose

disodium edetate

sodium hydroxide

isopropyl alcohol

purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

Polyethylene container with high density polyethylene closures, containing 100 ml of product.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/151/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th March 2015

10 DATE OF REVISION OF THE TEXT

January 2019