

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diprosalic 0.05% w/w + 3% w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The ointment contains 0.05% w/w betamethasone (as dipropionate) and 3% w/w salicylic acid.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment

Product imported from France:

Smooth, off-white ointment

4 CLINICAL PARTICULARS

As per PA1328/028/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1328/028/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
White soft paraffin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Epoxy-lined aluminium tubes with plastic caps, containing 30g of product.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare,
Unit 4, Bradfield Road,
Ruislip,
Middlesex, HA4 0NU,
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1328/075/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 13th July 2007

Date of Last Renewal: 13th July 2012

10 DATE OF REVISION OF THE TEXT

April 2015