

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Scheriproct 1.5 mg/g + 5 mg/g Rectal Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of ointment contains prednisolone caproate equivalent to 1.5 mg of prednisolone and 5 mg of cinchocaine hydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal Ointment

Product imported from the UK and Portugal

Colourless to faintly yellow homogeneous translucent ointment

4 CLINICAL PARTICULARS

As per PA1410/071/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/071/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Octyldodecanol
Castor oil, refined
Castor oil, hydrogenated
Polyethylene glycol-400-monoricinoleate
Chypre perfume oil

6.2 Incompatibilities

Not applicable

6.3 Shelf life

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

After first opening: 3 months

6.4 Special precautions for storage

Do not store above 25°C. Replace the cap tightly after use.

6.5 Nature and contents of container

Aluminium tubes with 30g of ointment in an over-labelled cardboard carton with a rectal cannula

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Ltd.
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st August 2012

10 DATE OF REVISION OF THE TEXT

August 2017