

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 1.9 mg prednisolone caproate equivalent to 1.5 mg of prednisolone and 5 mg of cinchocaine hydrochloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal ointment.

Product imported from Portugal:

Colourless to faintly yellow homogenous translucent ointment.

4 CLINICAL PARTICULARS

As per PA1407/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1407/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Octyldodecanol
Castor oil
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 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

30g tube and a rectal ointment applicator contained in an outer cardboard carton. Pack size 30g.

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
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HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1328/033/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 18 August 2006

Date of Last Renewal: 18 August 2011

10 DATE OF REVISION OF THE TEXT

January 2016