

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Scheriproct 1.5mg/g + 5mg/g rectal ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal ointment

Product imported from the UK:
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
Hydrogenated castor oil
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 tube and outer carton of the product on the market in the country of origin.

Shelf-life 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 in an outer carton or over-labelled outer carton.

Pack size: 1 x 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/123/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th October 2009

10 DATE OF REVISION OF THE TEXT

July 2018