

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bactroban Nasal Ointment 2% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mupirocin 2.0% w/w as mupirocin calcium.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal ointment.

Product sourced from the UK:

A smooth white ointment.

Product imported from Spain:

An ointment.

4 CLINICAL PARTICULARS

As per PA1077/094/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/094/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin

Mixed diglycerin ester of fatty acids (softisan 649)

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

Lacquered aluminium tube fitted with a nozzle and screw cap containing 3g white ointment.

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

Any product remaining at the end of treatment should be discarded.
Wash your hands after application.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/312/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th July 2013

10 DATE OF REVISION OF THE TEXT

December 2016