

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bactroban 2% w/w Nasal Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of nasal ointment contains 20 mg 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 Spain and Greece:
An off white smooth 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 3 g white ointment.

6.6 Special precautions for disposal

Any product remaining at the end of treatment should be discarded.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Wash your hands after application.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/312/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th July 2013
Last updated: December 2016

10 DATE OF REVISION OF THE TEXT

June 2022