

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bactroban 2% w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 20 mg mupirocin (2.0% w/w) as mupirocin free acid.

For the full list excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from Spain

Ointment in a white, translucent, water-soluble, macrogol base.

4 CLINICAL PARTICULARS

As per PA1077/094/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/094/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 400
Macrogol 3350

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 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

Sealed tamper evident aluminium tube containing 15 g 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

PPA0465/312/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th August 2021

10 DATE OF REVISION OF THE TEXT