

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bactroban Nasal Ointment 2.0% 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 imported from the United Kingdom:
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 is the date shown on the bottle and out carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube fitted with a nozzle and a screw cap containing 3g of 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/169/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th February 2012

10 DATE OF REVISION OF THE TEXT

November 2014