

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucibet 20 mg/g + 1 mg/g cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fusidic acid 20 mg/g and betamethasone 1 mg/g (as betamethasone valerate).

Excipients with known effect: contains cetostearyl alcohol and chlorocresol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from United Kingdom:

A white to off-white homogenous cream.

4 CLINICAL PARTICULARS

As per PA0046/040/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0046/040/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether
Cetostearyl alcohol
Chlorocresol
Liquid paraffin
Sodium dihydrogen phosphate
White soft paraffin
Purified water
Sodium hydroxide
all-rac- α -tocopherol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

No special precautions for use.

Store below 30°C

6.5 Nature and contents of container

Internally lacquered aluminium tube, sealed with an aluminium membrane and fitted with a white polyethylene screw cap.
Contents: 30 g cream.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/231/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th August 2009

Last updated: January 2014

Last updated: August 2015

10 DATE OF REVISION OF THE TEXT

July 2019