

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucibet 20mg/g & 1mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fusidic acid 20mg/g and betamethasone 1mg/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
Cetostearyl alcohol
Chlorocresol
Liquid paraffin
Sodium dihydrogen phosphate
White soft paraffin
Purified water
Sodium hydroxide

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 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/231/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th August 2009

10 DATE OF REVISION OF THE TEXT

September 2015