

# 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- $\alpha$ -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: 14<sup>th</sup> August 2009

Last updated: January 2014

Last updated: August 2015

## **10 DATE OF REVISION OF THE TEXT**

July 2019