

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Fucidin 20mg/g Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 20 mg fusidic acid.

Excipients with known effect: contains cetyl alcohol, potassium sorbate, butylhydroxyanisole (E320).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cream

*Product imported from Greece:*

A white, homogeneous cream

## 4 CLINICAL PARTICULARS

As per PA0046/004/012

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0046/004/012

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Butylhydroxyanisole (E320)

Cetyl alcohol

Glycerol

Liquid paraffin

Polysorbate 60

Potassium sorbate

Purified water

White soft paraffin

all-rac- $\alpha$ -tocopherol and hydrochloric acid for pH adjustment

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

After first opening: 28 days.

#### **6.4 Special precautions for storage**

Do not store above 25°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: 15 g and 30 g.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal**

No special requirements.

Any unused 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**

PPA0465/197/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 13 April 2007

Date of last renewal: 13 April 2012

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

August 2022