

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucidin 20 mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 20mg fusidic acid.

Excipients: Contains Butylhydroxyanisole (E320), Potassium Sorbate and cetyl alcohol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from Greece

A white 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- α -tocopherol

Hydrochloric acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the tube and outer carton 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 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.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/083/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th October 2013

10 DATE OF REVISION OF THE TEXT

October 2021