

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucibet Lipid 20mg/g + 1mg/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, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and potassium sorbate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from *Greece*

White cream

4 CLINICAL PARTICULARS

As per PA0046/040/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0046/040/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Steareth-21

Cetostearyl alcohol

Paraffin, white soft

Paraffin, liquid

Hypromellose

Citric acid, monohydrate

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Potassium sorbate

all-rac- α -tocopherol

Water, purified

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.

Discard any remaining cream 3 months after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube with white screw cap

Pack size: 30 g

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/197/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd February 2023

10 DATE OF REVISION OF THE TEXT