

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: contains cetostearyl alcohol and chlorocresol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the UK:

A white cream.

4 CLINICAL PARTICULARS

AS PER PA 046/040/001

5 PHARMACOLOGICAL PROPERTIES

AS PER PA 046/040/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol Cetostearyl Ether
Cetostearyl alcohol
Chlorocresol
Liquid paraffin
Sodium dihydrogen phosphate
White soft paraffin
Sodium hydroxide (for pH adjustment)
all-*rac*- α -tocopherol
Purified water

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 carton of the product on the market in the country of origin.

After first opening of container: 3 months

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Aluminium tubes fitted with a white polyethylene screw cap.

Contents: 30g 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

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

PPA1463/082/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th October 2013

10 DATE OF REVISION OF THE TEXT

April 2021