Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Keflex 500 mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg cefalexin anhydrous (as the monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK
Pillow-shaped, 16mm long, scored, peach, marked 'GP4'.

Scoreline is to facilitate breaking for ease of swallowing only.

4 CLINICAL PARTICULARS

As per PA1226/002/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1226/002/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Sodium Starch Glycollate
Magnesium Stearate
Povidone

Tablet coating:
Hypromellose
Glycerol
Talc
Titanium Dioxide E171
Iron Oxide Yellow E172
Iron Oxide Red E172

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Blister packs of 21 tablets in an over labeled outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/166/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th July 2012

10 DATE OF REVISION OF THE TEXT

August 2018