

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Keflex 250 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 250 mg cefalexin anhydrous (as the monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard Capsule

Product imported from the UK
Green and white capsule printed ‘GP1’.

4 CLINICAL PARTICULARS

As per PA1226/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1226/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose with sodium carboxymethyl cellulose
Dimeticone
Magnesium stearate

Capsule shell
Patent blue V (E131)
Quinoline yellow (E104)
Titanium dioxide (E171)
Gelatin

Printing Ink
Shellac
Black iron oxide

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 as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.
Store in the original package.

6.5 Nature and contents of container

Blister packs of 28 tablets (2 aluminium blister strips of 14 tablets) in an over labelled 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

PPA1151/166/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2012

10 DATE OF REVISION OF THE TEXT

August 2018