

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 (as monohydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the United Kingdom
Pillow shaped, 16 mm 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

Sodium Starch Glycolate (Type A)
Magnesium Stearate
Povidone
Methylhydroxypropylcellulose
Glycerol
Talc
Titanium dioxide
Iron oxide yellow
Iron oxide red
Cellulose with sodium carboxymethylcellulose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market 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

Blisters of 21 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/049/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th August 2018

10 DATE OF REVISION OF THE TEXT