Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Klacid LA 500 mg modified-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains clarithromycin 500 mg

Excipients with known effects: lactose and sodium

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified release tablet.
Product imported from the Czech Republic:
Yellow, ovaloid modified-release tablet.

4 CLINICAL PARTICULARS

As per PA2010/004/004

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/004/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid
Sodium alginate
Sodium calcium alginate
Lactose monohydrate
Povidone 40
Talc
Stearic acid 95%
Magnesium stearate
Hydroxypropyl methylcellulose
Macrogol 400
Macrogol 8000
Titanium dioxide
Sorbic acid
Quinoline yellow aluminium lake (E104)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the container 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.
Keep container in the outer carton in order to protect from light and moisture.

6.5 Nature and contents of container

7 tablets in a blister original pack.
The blisters are packaged in a cardboard carton with a pack insert.

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/051/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th July 2014

10 DATE OF REVISION OF THE TEXT

May 2019