Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Klacid Forte 500 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of clarithromycin

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the Czech Republic, Greece and Spain:
Yellow, ovaloid, film-coated tablets

Product imported from the Netherlands:
Yellow, ovaloid, film-coated tablets with a symbol embossed on one side and plain on the other side.

4 CLINICAL PARTICULARS

As per PA2010/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/004/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients present in the product imported from Greece:

Croscarmellose sodium
Microcrystalline cellulose
Pregelatinised starch
Silicon dioxide
Povidone
Stearic acid
Magnesium stearate
Talc
Hypromellose
Hyprolose
Propylene glycol
Sorbitan oleate
Titanium dioxide (E171)
Sorbic acid
Vanillin
Quinoline yellow (E104)

Excipients present in the product imported from the Netherlands:

Carmellose sodium

Microcrystalline cellulose
Pregelatinised starch
Silicon dioxide
Povidone
Stearic acid
Magnesium stearate
Talc
Hypromellose
Hyprolose
Propylene glycol
Sorbitan oleate
Titanium dioxide (E171)
Sorbic acid
Vanillin
Quinoline yellow (E104)

Excipients present in the product imported from Spain:

Croscarmellose sodium
Microcrystalline cellulose
Silicon dioxide
Povidone
Stearic acid
Magnesium stearate
Talc
Hypromellose
Hyprolose
Propylene glycol
Sorbitan oleate
Titanium dioxide (E171)
Sorbic acid
Vanillin
Quinoline yellow (E104)

Excipients present in the product imported from The Czech Republic:
Croscarmellose
microcrystalline cellulose
anhydrous colloidal silica
povidone 40
stearic acid 95%
magnesium stearate
talc
hypromellose
hydroxypropyl cellulose
propylene glycol
sorbitan oleate
titanium dioxide (E171)
vanillin
sorbic acid
aluminum lake quinoline yellow (E104)

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

6.4 Special precautions for storage

Store in the original package.

Do not store above 25°C
Store in the original packaging in order to protect from light.

6.5 Nature and contents of container

Blister packs containing 14 or 21 tablets.
Not all pack sizes may be marketed.

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 Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/051/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 January 2002

10 DATE OF REVISION OF THE TEXT

July 2016