

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cilest 250/35 microgram Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 250 micrograms norgestimate and 35 micrograms ethinylestradiol

Excipient: contains lactose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK

A dark blue, flat, bevel-edged tablet engraved “C” over “250” on both faces

4 CLINICAL PARTICULARS

As per PA0748/029/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/029/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose (anhydrous)

Magnesium Stearate

Pregelatinised starch

FD & C Blue No 2 Lake (132)

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 on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store blister in the outer carton to protect from light.

6.5 Nature and contents of container

Over-labelled cardboard carton containing 3 blister strips (21 tablets per strip).

Pack size of 3 x 21 tablets

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

B&S Healthcare
Unit 4, Bradfield Road
Ruislip
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HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/102/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th June 2009

10 DATE OF REVISION OF THE TEXT

October 2014