Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cerazette 75 microgram film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 75 microgram desogestrel.
Excipient(s) with known effect: Each tablet contains Lactose monohydrate.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK:
The tablet is white, round, biconvex and 5 mm in diameter. On one side it is coded KV above 2 and on the reverse side Organon*.

4 CLINICAL PARTICULARS

As per PA1286/048/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/048/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Silica, Colloidal anhydrous
All-rac-α-tocopherol
Lactose monohydrate
Maize starch
Povidone
Stearic acid

Film coating
Hypromellose
Macrogol 400
Talc
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of the product is the date shown on the container and outer carton of the product on the market in the country of origin.

Use within 1 month from the date of first opening of the sachet.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.

Store the blister pack in the original sachet in order to protect from light and moisture. For storage conditions after first opening the sachet, see section 6.3.

6.5 Nature and contents of container

Each blister contains 28 tablets. Each carton contains 1 PVC/aluminium blister packed separately in an aluminium laminated sachet.

6.6 Special precautions for disposal

The active substance etonogestrel shows an environmental risk to fish.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/071/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th February 2013

10 DATE OF REVISION OF THE TEXT

March 2018