

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cerazette 75 microgram film-coated tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 75 microgram desogestrel.

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from United Kingdom:

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 monhydrate

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 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. Shelf-life after first opening the sachet: 1 month.

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 1blister packed separately in a 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/307/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th May 2013

10 DATE OF REVISION OF THE TEXT

August 2016