

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cerazette 75 microgram film-coated tablet

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 75 micrograms desogestrel.  
Excipient of known effect: lactose monohydrate.  
For a 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- $\alpha$ -tocopherol  
Lactose monhydrate  
Maize starch  
Povidone  
Stearic acid

Film coating  
Hypromellose  
Macrogol 400  
Talc  
Titanium dioxide (E 171)

### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marked in the country of origin.

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

### **6.4 Special precautions for storage**

Store 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**

Cardboard outer containing a blister strip packed in an aluminium laminated sachet.

Pack size: 1 x 28 tablets

### **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/222/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

First date of authorisation: 13<sup>th</sup> June 2014

## **10 DATE OF REVISION OF THE TEXT**

October 2014