Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prevenelle 1500 microgram Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1500 micrograms of levonorgestrel.
Excipient with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from France
Almost white, flat, rimmed tablet of about 8 mm diameter with an impressed mark of “G00” on one side.

4 CLINICAL PARTICULARS

As per PA1330/021/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1330/021/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potato starch
Corn starch
Silica colloidal anhydrous
Magnesium stearate
Talc
Lactose monohydrate

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 carton of the product as marked in the country of origin

6.4 Special precautions for storage

Store in the original package in order to protect from light.

6.5 Nature and contents of container

Cardboard outer carton containing blister.
Pack size: 1 Tablet

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/249/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th August 2015

10 DATE OF REVISION OF THE TEXT

December 2016