

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Norlevo 1.5 mg tablet

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.5 mg levonorgestrel

Excipients with known effect: each tablet contains lactose monohydrate.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Tablet

*Product imported from France*

White, round biconvex tablet engraved with code NL 1.5 on one face.

### 4 CLINICAL PARTICULARS

As per PA1166/002/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1166/002/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Lactose monohydrate  
Maize starch  
Povidone  
Colloidal anhydrous silica  
Magnesium stearate

#### 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

Keep the blister in the outer carton in order to protect from light.

## **6.5 Nature and contents of container**

Blister pack of 1 tablet in an over labelled outer carton.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Primecrown 2010 Limited  
4/5 Northolt Trading Estate  
Belvue Road  
Northolt  
Middlesex UB5 5QS  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1633/025/001

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

Date of first authorisation: 16th November 2012

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

July 2017