

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

NorLevo 1.5 mg tablet

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.5mg levonorgestrel.

Excipients: lactose monohydrate.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Tablet

*Product imported from Italy:*

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 is the date shown on the blister and outer carton of the product as marketed 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 strip of 1 tablet in an over labelled carton.

## **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**

PPA 1151/177/001

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

Date of first authorisation: 2<sup>nd</sup> March 2012

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

July 2015