

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Noctamid 1mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1mg lormetazepam.

Excipient(s) with known effect: lactose

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from Spain*

Round, white tablet with ‘CF’ imprinted in a hexagon on one face and a breakline on the reverse.  
The tablet can be divided into equal halves.

## 4 CLINICAL PARTICULARS

As per PA1410/009/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1410/009/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose  
Magnesium stearate  
Maize starch  
Povidone 25000

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blisters and outer carton of the product as marketed in the country of origin.

### 6.4 Special precautions for storage

Do not store above 25°C.

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

Aluminium blisters, 3 blisters strips, each containing 10 tablets in a cardboard outer carton.

Pack size: 30 tablets

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/192/001

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

Date of first authorisation: 5th April 2013

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

October 2014