

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Noctamid 1 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains lormetazepam 1mg

Excipient with a known effect: contains lactose (as monohydrate)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Spain:*

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

## 4 CLINICAL PARTICULARS

As per PA 1410/009/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 1410/009/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate  
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 container and outer package of the product on the market in the country of origin.

### 6.4 Special precautions for storage

Do not store above 25°C.

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

Blister strips, 10 tablets/strip, in a cardboard 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**

PCO Manufacturing  
Unit 10  
Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/402/001

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

Date of first authorisation: 10<sup>th</sup> October 2014

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

June 2016