

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nurofen 200 mg Coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200mg ibuprofen.  
Excipients with known effect: sucrose and sodium

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Coated Tablet

*Product imported from UK*  
White round sugar-coated tablet with ‘NUROFEN’ imprinted in black.

## 4 CLINICAL PARTICULARS

As per PA0979/032/006

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0979/032/006

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet Core  
Sodium Citrate  
Croscarmellose Sodium  
Stearic Acid  
Silicon dioxide  
Sodium laurilsulphate

Tablet Coat:  
Sucrose  
Talc  
Carmellose Sodium  
Titanium Dioxide (E171)  
Acacia  
Macrogol  
Black Printing Ink (contains shellac, iron oxide black (E172) and propylene glycol)

### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf life expiry date of this product is the date shown on the blister strip and outer carton of the product as marked in the country of origin.

### **6.4 Special precautions for storage**

Do not store above 25°C. Store in the original pack.

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

Cardboard outer carton containing blister strip.  
Pack size: 12 or 24 tablets

Not all pack sizes may be marketed.

### **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  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/245/001

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

Date of first authorisation: 27<sup>th</sup> March 2015

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