

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Celebrex 200mg Hard Capsules

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 200 mg celecoxib.  
Excipient: Lactose monohydrate  
For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Hard Capsule.  
*Product imported from Portugal*  
Opaque, white capsule with two gold bands marked '7767' and '200'.

### 4 CLINICAL PARTICULARS

As per PA0822/116/002

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/116/002

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Capsule contents:

Lactose monohydrate  
Sodium laurilsulfate  
Povidone  
Croscarmellose sodium  
Magnesium stearate

Capsule shell:

Gelatin  
Titanium dioxide (E171)  
Sodium laurilsulfate  
Sorbitan monolaurate

Printing ink:

Iron oxide (E172)  
Shellac  
Propylene glycol

#### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf life expiry date for 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 30°C.

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

Blister strips in a repackaged carton containing 30 capsules.

### **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**

PPA1151/070/001

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

Date of first authorisation: 1st August 2008

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

October 2014