

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Arcoxia 30mg Film-coated Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 30mg of etorcoxib.

Excipients: also contains lactose monohydrate.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Film-coated Tablet.

*Product imported from France*

Blue-green, apple-shaped biconvex tablets debossed '101' on one side and 'ACX 30' on the other side.

### 4 CLINICAL PARTICULARS

As per PA1997/001/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1997/001/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

*Core:*

Calcium hydrogen phosphate (anhydrous)

Croscarmellose sodium

Magnesium stearate

Microcrystalline cellulose

*Tablet coating:*

Carnauba wax

Lactose monohydrate

Hypromellose

Titanium dioxide (E171)

Triacetin

Indigo carmine lake (E132)

Yellow ferric oxide (E172)

#### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf-life expiry date of this product is the date shown on the blister strips and outer carton of the product on the market in the country of origin.

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

Store in the original package in order to protect from moisture.

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

Overlabelled cardboard outer containing blister strips.

Pack size: 28 film-coated 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 Ltd.  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/137/001

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

Date of first authorisation: 6th of August 2010

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

February 2017