

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Arcoxia 120mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 120mg of etoricoxib.  
Excipient(s) with know effect: also contains lactose monohydrate.  
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Romania:*

Pale-green, apple-shaped, biconvex tablets marked 'Arcoxia 120' on one side and '204' on the other.

## 4 CLINICAL PARTICULARS

As per PA1997/001/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1997/001/004

## 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 as marketed in the country of origin.

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

Do not store above 25°C.  
Store in the original package in order to protect from moisture.

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

Cardboard carton containing blister strips.  
Pack size: 28

#### **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  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/137/004

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

Date of first authorisation: 8<sup>th</sup> April 2016

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