

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Arcoxia 60 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 60 mg of etoricoxib.

Excipients with known effect:

60 mg tablet: 2.7 mg lactose

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated Tablet (tablets).

*Product imported from Romania:*

Dark green, apple-shaped, biconvex film-coated tablets debossed '200' on one side and 'ARCOXIA 60' on the other side.

## 4 CLINICAL PARTICULARS

As per PA0964/009/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0964/009/002

## 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 below 25° C. Store in the original package in order to protect from moisture.

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

Aluminium/aluminium blisters in over-labelled cardboard cartons containing 28 tablets.

#### **6.6 Special precautions for disposal and other handling**

No special requirements

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

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

PPA1463/041/001

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

Date of first authorisation: 6<sup>th</sup> August 2010

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

November 2021