

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Arcoxia 90 mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 90 mg of etoricoxib.  
Excipient with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).

*Product imported from ROMANIA:*  
White, apple-shaped, biconvex tablets debossed '202' on one side and 'ARCOXIA 90' on the other side.

## 4 CLINICAL PARTICULARS

As per PA 1286/007/003.

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 1286/007/003.

## 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

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer packaging 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**

Blister strips of 7 tablets in an outer cardboard carton.  
Pack size: 28 tablets.

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

No special requirements.

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

Clear Pharmacy  
157-173 Roden Street  
Belfast BT12 5QA  
United Kingdom

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

PPA1596/043/002

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

Date of first authorisation: 8th April 2011

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

September 2015