

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Arcoxia 120 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 120mg of etoricoxib

Excipient(s) with known effect

Lactose monohydrate

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Greece*

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

## 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

These tablets also contain indigo carmine lake (E132) and yellow ferric oxide (E172).

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

The shelf life expiry date of this product shall be the date shown on the blister and outer package 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**

Blisters of 14 tablets

## **6.6 Special precautions for disposal**

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Primecrown 2010 Limited  
4/5 Northolt Trading Estate  
Belvue Road  
Northolt  
Middlesex UB5 5QS  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1633/045/004

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

Date of first authorisation: 3<sup>rd</sup> February 2012

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

November 2018