

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.

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 Portugal

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

4 CLINICAL PARTICULARS

As per PA1997/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1997/001/002

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 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 20 or 28 tablets.
Not all pack sizes may be marketed.

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

PPA1633/045/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th May 2012

10 DATE OF REVISION OF THE TEXT

March 2017