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 (as monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Spain, Greece and Romania:
White, apple-shaped, biconvex film-coated tablets marked 'Arcoxia 90' on one side and '202' on the other.

Product imported from Italy:
White apple-shaped, biconvex, film-coated tablets which are marked with 'ARCOXIA 90' on one side and '202' on the other.

Or

White apple-shaped, biconvex, film-coated tablets which are blank on one side and marked with '202' on the other.

4 CLINICAL PARTICULARS

As per PA0964/009/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0964/009/003

5.1 Pharmacodynamic properties

M01AH
M01AH05

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 is the date shown on the container 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. Do not store above 25° C.

6.5 Nature and contents of container

Blisters in packs containing 28 or 30 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 the local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/176/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 April 2006

Date of last renewal: 07 April 2011

10 DATE OF REVISION OF THE TEXT

June 2022