

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arcoxia 30 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 30mg of etoricoxib.

Excipient with known effect: lactose (as monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets (tablets)

Product imported from France:

Blue-green, apple-shaped biconvex tablets debossed '101' on one side and 'ACX 30' on the other side.

4 CLINICAL PARTICULARS

As per PA0964/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0964/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Calcium hydrogen phosphate (anhydrous)

Croscarmellose sodium

Magnesium stearate

Microcrystalline cellulose

Tablet coating:

Camauba 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 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.

6.5 Nature and contents of container

Aluminium blisters in packs containing 28 tablets

6.6 Special precautions for disposal and other handling

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

PPA0465/176/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th of October 2010

10 DATE OF REVISION OF THE TEXT

June 2022