

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 120 mg 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 Greece and Romania:

Pale-green, apple-shaped, biconvex film-coated tablets marked 'Arcoxia 120' on one side and '204' on the other .

4 CLINICAL PARTICULARS

As per PA 0964/009/004

5 PHARMACOLOGICAL PROPERTIES

As per PA 0964/009/004

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

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 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

Do not store above 25°C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Aluminium/aluminium blisters in packs containing 28 tablets.

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

PPA0465/176/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 April 2006

Date of last renewal: July 2015

10 DATE OF REVISION OF THE TEXT

June 2022