

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 with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).

Product imported from ROMANIA:

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

4 CLINICAL PARTICULARS

As per PA 1286/007/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA 1286/007/002.

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 date shown on the container and outer packaging of the product on the market in the country of origin.

6.4 Special precautions for storage

Store below 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister strips of 7 tablets in an outer cardboard carton.

Pack size: 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
157-173 Roden Street
Belfast BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1596/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 2011

10 DATE OF REVISION OF THE TEXT

September 2015