

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 120mg of etoricoxib.

Excipients 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 Greece

120 mg Tablets: Pale-green, apple-shaped, biconvex tablets debossed ‘204’ on one side and ‘ARCOXIA 120’ on the other side.

4 CLINICAL PARTICULARS

As per PA1997/001/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1997/001/004

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 (E 132)
Yellow ferric oxide (E 172)

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

Aluminum/aluminium blisters in packs containing 28 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/080/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd November 2014

10 DATE OF REVISION OF THE TEXT

December 2016