

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 60mg of etoricoxib.

Excipients with known effect:

lactose monohydrate

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet/tablet.

Product imported from Italy

60 mg Tablets: Dark green, apple-shaped, biconvex tablets debossed '200' on one side and plain on the other side.

4 CLINICAL PARTICULARS

As per PA1997/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1997/001/002

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.

Yellow ferric oxide (E172)

Indigo carmine lake (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Aluminum/aluminium blisters in packs containing 30 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/080/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st June 2012

10 DATE OF REVISION OF THE TEXT

December 2016