

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arcoxia 60mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 60mg of etorcoxib.

Excipients: also contains lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet.

Product imported from France:

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

Product imported from Italy:

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

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 blister strips and outer carton 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

Cardboard carton containing blister strips.

Pack size: 28 or 30 film-coated 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

Imbat Ltd.
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/137/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th of August 2010

10 DATE OF REVISION OF THE TEXT

July 2016