

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ARCOXIA 90mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 90mg of etoricoxib.
Excipients with known effect: lactose monohydrate
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from: Hungary and Spain

White, apple-shaped, biconvex tablets debossed '202' on one side and 'ARCOXIA 90' on the other side.

Product imported from: Italy

White, apple-shaped, biconvex tablets debossed '202' on one side and plain on the other side.

4 CLINICAL PARTICULARS

As per PA1286/007/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/007/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Hungary & Spain:

Core:

Calcium hydrogen phosphate anhydrous
Croscarmellose sodium
Magnesium stearate
Microcrystalline cellulose

Tablet coating:

Carnauba wax
Lactose monohydrate
Hypromellose
Titanium dioxide (E171)
Triacetin

Product imported from Italy:

Core:

Calcium phosphate dibasic anhydrous
Croscarmellose sodium
Magnesium stearate
Microcrystalline cellulose

Tablet coating:

Carnauba wax
Lactose monohydrate
Hypromellose
Titanium dioxide (E171)
Triacetin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton of the product as marketed 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 blisters in packs containing 28 or 30 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/137/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th June 2012

10 DATE OF REVISION OF THE TEXT

September 2015