

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arcoxia 120mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 120mg of etoricoxib.
Excipient(s) with know effect: also contains lactose monohydrate.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Romania:
Pale-green, apple-shaped, biconvex tablets marked ‘Arcoxia 120’ on one side and ‘204’ on the other.

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 (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 as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.
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

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/137/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 2016

10 DATE OF REVISION OF THE TEXT