

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Celebrex 100 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100 mg celecoxib.

Excipient(s) with known effect: Lactose

For the full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Product imported from Belgium, Greece and France

Hard Capsule.

Opaque, white capsule with two blue bands marked '7767' and '100'.

4 CLINICAL PARTICULARS

As per PA23055/006/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/006/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contains

Lactose monohydrate

Sodium laurilsulfate

Povidone K30

Croscarmellose sodium

Magnesium stearate

Capsule shells contain

Gelatin

Titanium dioxide (E171)

Sodium laurilsulfate

Sorbitan monolaurate

Printing Ink

Shellac

Propylene glycol

Indigotine (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Do not store above 30°C.

6.5 Nature and contents of container

Blister packs of 20, 30 or 60 capsules in a cardboard carton.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/118/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th March 2004

Date of last renewal: 19th March 2009

10 DATE OF REVISION OF THE TEXT

November 2021