Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Celebrex 200 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 200 mg celecoxib.

Excipient(s) with known effect: Lactose
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

Product imported from France, Italy, Poland and Greece
Opaque, white capsule with two yellow bands marked '7767' and '200'.

4 CLINICAL PARTICULARS

As per PA23055/006/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/006/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsules content:
Lactose monohydrate
Sodium laurilsulfate
Povidone K30
Croscarmellose sodium
Magnesium stearate

Capsule shells:
Gelatin
Titanium dioxide (E171)
Sodium laurilsulfate
Sorbitan monolaurate

Printing ink:
Shellac
Propylene glycol
Iron oxide (E172)

Product sourced from Poland also contains the following excipients;
Shellac, ethanol, anhydrous isopropyl alcohol, butyl alcohol, propylene glycol and ammonium hydroxide.

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 pack of 10, 20 or 30 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

PPA0465/118/002

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