Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen 200 mg coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains ibuprofen 200 mg.

Excipient(s) with known effect: Each tablet contains sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet.

Product imported from the Czech Republic and Lithuania
White, biconvex, coated tablets with "NUROFEN" printed in black on one side.

4 CLINICAL PARTICULARS

As per PA0979/032/006

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/032/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Citrate
Croscarmellose Sodium
Stearic Acid
Colloidal anhydrous silica
Sodium Laurilsulphate
Sucrose
Talc
Carmellose Sodium
Titanium Dioxide
Acacia spray dried
Macrogol 6000
Black Printing Ink
(iron oxide black (E172), propylene glycol (E1520), shellac)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Blister containing 12 tablets packed into cardboard cartons, containing 12, 24 or 48 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/430/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2017

Date of last renewal: 25th June 2021

10 DATE OF REVISION OF THE TEXT

July 2023