Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Express Maximum Strength 400 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ibuprofen 400 mg (as sodium dihydrate)

Excipients with known effect: Each tablet contains sucrose and sodium.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Coated Tablet.

Product imported from Lithuania:
A white to off-white, biconvex, round, sugar coated tablet with an identifying logo in red on one face.

4 CLINICAL PARTICULARS

As per PA0979/032/011

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/032/011

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium (E468)
Xylitol (E967)
Microcrystalline cellulose (E460)
Magnesium stearate (E572)
Colloidal anhydrous silica (E551)
Carmellose sodium (E466)
Talc (E553b)
Acacia spray dried (E414)
Sucrose
Titanium dioxide (E171)
Macrogol 6000 powder
Red print ink*

*(containing: Shellac (E904), iron oxide red (E172), ammonium hydroxide (E257) and simethicone)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The blisters are packed into cardboard cartons. Each pack may contain 12 or 24 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

PPA0465/430/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th August 2017

10 DATE OF REVISION OF THE TEXT

December 2023