Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each liquid capsule contains 400 mg ibuprofen.

Excipient(s) with known effect: Sorbitol Ponceau 4R (E124)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule soft

Product imported from Czech Republic: An oval shaped clear capsule with a translucent red gelatin shell, containing a clear liquid, printed with 'NUROFEN' in white.

4 CLINICAL PARTICULARS

As per PA0979/032/012

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/032/012

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents Macrogol 600 Potassium hydroxide Purified water Medium chain triglycerides Isopropyl alcohol Lecithin

<u>Capsule shell</u> Gelatin Dehydrated sorbitol Purified water Ponceau 4R (E124)

<u>Printing ink</u> Opacode WB white NS-78-18011 (contains titanium dioxide (E171), propylene glycol, and hypromellose 2910/3)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

26 January 2024

CRN00DW6C

Health Products Regulatory Authority

The shelf life expiry date of this product is the date shown on the blister and outer package of the product on the market in thecountry of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Blister packs of 20 capsules contained in an outer cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/220/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th January 2024

10 DATE OF REVISION OF THE TEXT