Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each liquid capsule contains 400mg ibuprofen.
Excipient(s) with known effect:
Sorbitol
Ponceau 4R (E124),
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule soft

Product imported from Poland.
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 PA0979/32/13.

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/32/13.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents
Macrogol 600
Potassium hydroxide (for pH adjustment)

Capsule shell
Gelatin
Sorbitol liquid, partially dehydrated
Purified water
Ponceau 4R (E124)
Lecithin, isopropyl alcohol, and medium chain triglycerides.

Printing ink
Opacode WB white NS-78-18011 (contains the following materials titanium dioxide propylene glycol, isopropyl alcohol and HPMC 2910/Hypromellose 3cP.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

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 the country 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

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2022

10 DATE OF REVISION OF THE TEXT