Health Products Regulatory Authority

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 95.68 mg per capsule and Ponceau 4R (E124).

For a 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 PA0979/032/013

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/032/013

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents

Macrogol 600

Potassium hydroxide

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 (E171) propylene glycol 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

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6.4 Special precautions for storage

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

6.5 Nature and contents of container

Each blister contains 20 capsules. The blisters are packed in a 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

PPA23176/057/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th January 2023

10 DATE OF REVISION OF THE TEXT

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