

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 400mg (as sodium dihydrate)

Excipient(s) with known effect:

Each tablet contains sucrose and sodium.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Coated Tablet.

Product imported from Latvia:

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 (E458)

Magnesium stearate (E572)

Xylitol (E967)

Sucrose

Titanium dioxide (E171)

Microcrystalline cellulose (E460)

Colloidal anhydrous silica (E551)

Carmellose sodium (E466)

Talc (E553b)

Acacia gum (E414)

Macrogol 6000.

Red printing ink*

*(contains: Shellac, Red iron oxide (E172), Propylene glycol, Ammonium hydroxide 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.

6.6 Special precautions for disposal and other handling

Not applicable.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/217/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd May 2024

10 DATE OF REVISION OF THE TEXT