

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 186.2 mg of sucrose and 48.6 mg (2.12 mmol) of sodium

For the full list of the excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Coated Tablet (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

This medicinal product contains 48.6 mg sodium per tablet, equivalent to 2.43% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/032/011

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium

Xylitol

Microcrystalline cellulose

Magnesium stearate

Colloidal anhydrous silica

Carmellose sodium

Talc

Acacia spray dried

Sucrose

Titanium dioxide (E171)

Macrogol 6000

Red print ink (Opacode S-1-15094) *

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

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed 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

Blister package re-boxed into cartons: Pack size 12 or 24 coated 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/270/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th December 2019

10 DATE OF REVISION OF THE TEXT