# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nurofen Cold & Flu film-coated tablets Ibuprofen 200mg Pseudoephedrine hydrochloride 30mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| Active Ingredients | Quantity |
|---|---|
| Ibuprofen | 200 mg |
| Pseudoephedrine Hydrochloride | 30 mg |

Excipient with known effect: Sunset yellow (E110)
For the full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Film coated tablet
*Product imported from Greece and Poland:*
Yellow, circular, biconvex, tablets printed in black with an identifying motif.

## 4 CLINICAL PARTICULARS

As per PA 0979/033/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 0979/033/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Product imported from Greece
Core:
Tricalcium Phosphate
Microcrystalline Cellulose
Povidone
Croscarmellose Sodium
Magnesium stearate

Film Coating:
Hypromellose
Talc
Opaspray yellow M-1F-6168 or
Mastercoat Yellow FA 0156

Black printing Ink:
Black iron oxide (E172)
Propylene glycol
N-butyl alcohol
Dehydrated ethanol
Isopropyl alcohol
Shellac glaze

Product imported from Poland
Core:

Calcium phosphate
Microcrystalline cellulose
Povidone
Croscarmellose sodium
Magnesium stearate

Film coating:
Hypromellose
Talc
Opaspray yellow M-1F-6168 or
Mastercoat Yellow FA 0156 containing:
Titanium dioxide (E171)
Sunset yellow (E110)
Quinoline yellow (E104)

Printing ink:
Iron oxide black (E172)
Propylene glycol
Shellac

**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**

Do not store above 25 °C.
Store in the original package in order to protect from moisture.

**6.5 Nature and contents of container**

A pack consisting of a blister containing 12 tablets. One or two blisters packed in a cardboard carton (12 or 24 tablets).
Not all pack sizes may be marketed.

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/337/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 24th November 2014

**10 DATE OF REVISION OF THE TEXT**

November 2021