

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

<u>Active Ingredients</u>	<u>Quantity</u>
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 PA0979/033/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/033/001

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

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th November 2014

10 DATE OF REVISION OF THE TEXT

December 2024