

# 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
Psuedoephedrine 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:*  
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

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

## **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  
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: 24<sup>th</sup> November 2014

## **10 DATE OF REVISION OF THE TEXT**

May 2016