

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nurofen for Children Orange 100 mg/5 ml oral suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 100 mg/5 ml (equivalent to 2.0% w/v)

### Excipients with known effect

Maltitol syrup

Sodium

Wheat starch

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral suspension

*Product imported from Greece*

An off-white orange flavoured syrupy suspension.

## 4 CLINICAL PARTICULARS

As per PA0979/032/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0979/032/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Maltitol syrup

Citric acid

Sodium citrate

Sodium chloride

Sodium saccharin

Domiphen bromide

Polysorbate 80

Xanthan gum

Orange flavour (contains wheat starch)

Glycerin

Purified Water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for 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**

No special storage requirement.

#### **6.5 Nature and contents of container**

Amber-coloured bottle with a child-resistant closure fitted with a liner. The bottle contains 150 ml of product. The bottle has an insert included in the bottleneck to facilitate the use of the syringe.

The product is supplied with the following dosing device:

O A 5 ml oral dosing syringe, comprised of an orange piston and a clear barrel.

#### **6.6 Special precautions for disposal and other handling**

Shake the bottle before use.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/337/001

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

Date of first authorisation: 15<sup>th</sup> August 2014

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

December 2025