

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Nurofen for Children Orange 100mg/5ml Oral Suspension

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of suspension contains 100 mg Ibuprofen (equivalent to 2% w/v).

Also contains maltitol syrup and sodium.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Oral suspension.

*Product imported from Spain:*

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  
Glycerol (E422)  
Purified water

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

The shelf life expiry date of this product shall be 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**

Amber-coloured 150 ml bottle with a 5 ml oral dosing syringe in an cardboard outer carton.

## **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**

Shake the bottle thoroughly before use.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/196/001

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

Date of first authorisation: 11<sup>th</sup> October 2013

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

January 2015