

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Non-drowsy Sinutab Tablets  
Paracetamol 500mg  
Pseudoephedrine hydrochloride 30mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 30 mg Pseudoephedrine hydrochloride and 500 mg Paracetamol.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablets

*Tablets imported from the UK:*  
White, round, biconvex tablets, plain on both sides.

## 4 CLINICAL PARTICULARS

As per PA0823/005/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0823/005/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose  
Pregelatinised maize starch  
Crospovidone  
Sodium starch glycolate (Type A)  
Povidone  
Stearic acid  
Magnesium stearate

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is 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

Do not store above 25°C. Store in the original packaging.

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

Over-labelled carton containing blister strip.  
Pack size: 15 tablets

## **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/114/001

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

Date of first authorisation: 31<sup>st</sup> July 2009

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

June 2018