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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Product imported from the UK:
White round biconvex tablet.

4 CLINICAL PARTICULARS

As per PA0330/038/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0330/038/001

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 container and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store below 25 ˚C. Store in the original package.

6.5 Nature and contents of container

Opaque white PVC and PVDC/Aluminium foil blister.
Packs of 15 tablets

6.6 Special precautions for disposal

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/184/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th September 2006
Date of last renewal: 8th September 2011
Date of last review: January 2014
Last updated: August 2016
Last updated: August 2018
Last updated: October 2020

10 DATE OF REVISION OF THE TEXT

August 2021