

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a 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 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 Glycollate
Povidone K30
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

Do not store above 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 contained in an outer cardboard 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

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

10 DATE OF REVISION OF THE TEXT

October 2016