

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 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

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: 31st July 2009

10 DATE OF REVISION OF THE TEXT

September 2016