

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Non-Drowsy Sudafed Decongestant 60mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 60mg of pseudoephedrine hydrochloride.

Excipient: Contains lactose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from the UK:

Reddish-brown, round, biconvex film-coated tablets, with 'SUDAFED' on one side, plain on the other.

4 CLINICAL PARTICULARS

As per PA0823/009/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0823/009/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize starch
Microcrystalline cellulose
Magnesium Stearate
Silica
Hyromellose
Red iron oxide (E172)
Talc
Polyethylene glycol

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 strip 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 container in order to protect from light.

6.5 Nature and contents of container

Over-labelled carton containing blister strips.

Pack size: 12 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 Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/131/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th September 2009

10 DATE OF REVISION OF THE TEXT

July 2018