

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stilnoct 5 mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5mg zolpidem tartrate

Excipients include: lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK:

Round, white, film-coated tablet with no markings.

4 CLINICAL PARTICULARS

As per PA0540/160/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/160/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Microcrystalline cellulose

Hypromellose

Sodium starch glycollate

Magnesium stearate

Macrogol 400

Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the carton and blister-foil.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Cardboard outer containing blister strips.

Pack size: 28 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
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/030/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th March 2009

10 DATE OF REVISION OF THE TEXT

January 2019