

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stilnoct 10mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains: Zolpidem tartrate 10mg

Excipient(s) with known effect

Lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK

Oblong, white, scored tablet engraved 'SN10' on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA0540/160/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/160/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Lactose Monohydrate

Microcrystalline cellulose

Hypromellose

Sodium starch glycollate

Magnesium stearate

Film coating

Macrogol 400

Titanium dioxide (E171)

Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Store in a dry place in the original packaging. Do not store above 30°C.

6.5 Nature and contents of container

PVC/foil blister strips in a cardboard outer carton. 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

PPA1151/030/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 May 2007

Date of last renewal: 04 May 2012

10 DATE OF REVISION OF THE TEXT

April 2018