

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'.

4 CLINICAL PARTICULARS

As per PA0540/160/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/160/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Hypromellose
Sodium starch glycolate
Magnesium stearate
Titanium dioxide (E171)
Macrogol 400

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 carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store below 30°C in the original packaging.

6.5 Nature and contents of container

Carton of 28 tablets in blister strips.

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

PPA0465/420/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th January 2017

10 DATE OF REVISION OF THE TEXT

May 2018