

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Provigil 200 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200mg of modafinil.

Excipient: Each tablet contains anhydrous lactose.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:

The tablets are white to off-white, 16 x 7 mm, capsule-shaped and debossed with “200” on one side.

4 CLINICAL PARTICULARS

As per PA0749/198/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/198/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Pregelatinised starch (maize)
Microcrystalline cellulose
Croscarmellose sodium
Povidone K29/32
Magnesium stearate

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister Packs of 30 tablets in a cardboard carton.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/415/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th June 2015

10 DATE OF REVISION OF THE TEXT