

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Provigil 200 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200 mg of modafinil.

Excipient(s) with known effects:
Each tablet contains anhydrous lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from The United Kingdom

The tablets are white to off-white, 16 x 7mm, 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 for this product shall be the date shown on the blister 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

Aluminium blisters. Packs of 30 tablets.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
Unit 18
Oxleasow Road
East Moons Moat
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B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th August 2017

10 DATE OF REVISION OF THE TEXT