Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Provigil 100 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100mg modafinil.

Excipient(s) with known effect: lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from UK

The tablets are white to off-white, 13 x 6 mm, capsule-shaped and debossed with “100” on one side.

4 CLINICAL PARTICULARS

As per PA0749/198/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/198/001

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 is the date shown on the blister strip and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

This medicine does not require any special storage conditions.

6.5 Nature and contents of container

Cardboard outer carton containing blister strips.
Pack size: 30 tablets

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/267/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th August 2018

10 DATE OF REVISION OF THE TEXT