

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Provigil 100 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg of modafinil.

Excipient(s) with known effect:

Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Spain:*

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 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**

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

#### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

#### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/115/001

#### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 26<sup>th</sup> September 2017

#### **10 DATE OF REVISION OF THE TEXT**

September 2021