

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Provigil 100 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100mg modafinil.

Excipients: contains lactose.

For a 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 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 containing 10 tablets. Packs containing 30 tablets.

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

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/041/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2011

10 DATE OF REVISION OF THE TEXT

August 2015