# MODAFINIL 200 MG TABLETS
# PL 04569/1367

## UKPAR

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## LAY SUMMARY

On 03 April 2013, the MHRA granted Generics (UK) Limited a Marketing Authorisation (licence) for the medicinal product Modafinil 200 mg Tablets (PL 04569/1367). This is a prescription-only medicine (legal status POM) and can be taken by adults who suffer from narcolepsy to help them to stay awake. Narcolepsy is a condition that causes excessive daytime sleepiness and a tendency to fall asleep suddenly in inappropriate situations (sleep attacks).

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Modafinil 200 mg Tablets outweigh the risks; hence a Marketing Authorisation has been granted.

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## SCIENTIFIC DISCUSSION

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# INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation to Generics (UK) Limited for the medicinal product Modafinil 200 mg Tablets (PL 04569/1367) on 03 April 2013. This is a prescription-only medicine (legal status POM) and is used to treat excessive sleepiness associated with narcolepsy with or without cataplexy. Excessive sleepiness is defined as difficulty maintaining wakefulness and an increased likelihood of falling asleep in inappropriate situations.

This was submitted as an abridged simple application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Modafinil 200 mg Tablets (PL 22805/0029), which was granted to the Marketing Authorisation Holder Orchid Europe Limited on 22 January 2010.

The product contains the active substance modafinil, which is a $\alpha_1$-adrenergic agonist and promotes wakefulness in a variety of species, including man. The precise mechanism(s) through which modafinil promotes wakefulness is unknown.

# PHARMACEUTICAL ASSESSMENT

**LICENCE NO:** PL 04569/1367
**PROPRIETARY NAME:** Modafinil 200 mg Tablets
**ACTIVE(S):** Modafinil
**COMPANY NAME:** Generics (UK) Limited
**E.C. ARTICLE:** Article 10c
**LEGAL STATUS:** POM

## 1. INTRODUCTION

This is a simple, piggyback application for Modafinil 200 mg Tablets, submitted under Article 10c of Directive 2001/83/EC as amended. The proposed MA holder is Generics (UK) Limited, Albany Gate, Darkes Lane, Potters Bar, Hertfordshire, EN6 1AG, England.

The application cross-refers to Modafinil 200 mg Tablets (PL 22805/0029), which was granted to the Marketing Authorisation Holder Orchid Europe Limited on 22 January 2010.

The current application is considered valid.

## 2. MARKETING AUTHORISATION APPLICATION FORM

### 2.1 Name(s)

The proposed name of the product is Modafinil 200 mg Tablets. The product has been named in-line with current requirements.

### 2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Each tablet contains 200 mg modafinil.

The finished product is packaged in polyvinylchloride-Aclar/Aluminium foil blisters in cardboard cartons. Approved pack sizes are 10 and 30 tablets.

Not all pack sizes are to be marketed, however, the applicant has committed to submitting mock-ups for approval before marketing any pack size.

The proposed shelf-life (2 years) and storage conditions (no specific storage instructions) are consistent with the details registered for the cross-reference product.

### 2.3 Legal status

On approval, the product will be available as a prescription-only medicine (POM).

### 2.4 Marketing authorisation holder/Contact Persons/Company

Generics (UK) Limited, Albany Gate, Darkes Lane, Potters Bar, Hertfordshire, EN6 1AG, England.

The QP responsible for pharmacovigilance is stated and their CV is included.

### 2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

### 2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

### 2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product.

### 2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product.

### 2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

### 2.10 TSE Compliance
No materials of animal or human origin are included in this product. This is consistent with the cross-reference product.

### 2.11 Bioequivalence
No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Modafinil 200 mg Tablets (PL 22805/0029).

## 3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

## 4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

## 5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed SmPC is consistent with the details registered for the cross-reference product.

## 6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference product. It was submitted to the MHRA along with results of consultations with target patient groups ('user testing'), in accordance with Article 59

of Council Directive 2001/83/EC, as amended. The results indicate that the leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In-line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

## 7. CONCLUSIONS

The data submitted with the application is acceptable. From a quality perspective, a Marketing Authorisation should be granted.

## NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with this application and none are required for applications of this type.

## CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for applications of this type.

## OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

### QUALITY

The important quality characteristics of Modafinil 200 mg Tablets are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

### NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

### CLINICAL PHARMACOLOGY/EFFICACY

No new clinical pharmacology/efficacy data have been submitted with this application and none are required for applications of this type.

### SAFETY

No new safety data have been submitted with this application and none are required for applications of this type.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory.

## BENEFIT-RISK ASSESSMENT

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with Modafinil 200 mg Tablets is considered to have demonstrated the therapeutic value of the compound. The benefit-risk is, therefore, considered to be positive.

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## STEPS TAKEN FOR ASSESMENT

| | |
|---|---|
| 1 | The MHRA received the marketing authorisation application on 19 July 2012. |
| 2 | Following standard checks and communication with the applicant, the MHRA considered the application valid on 24 July 2012. |
| 3 | Following assessment of the application, the MHRA requested further information relating to the dossier on 21 September 2012, 18 January 2013 and 11 March 2013. |
| 4 | The applicant responded to the MHRA's requests, providing further information on 30 November 2012, 08 March 2013 and 13 March 2013. |
| 5 | The application was determined on 03 April 2013. |

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## STEPS TAKEN AFTER AUTHORISATION - SUMMARY

| Date submitted | Application type | Scope | Outcome |
|---|---|---|---|
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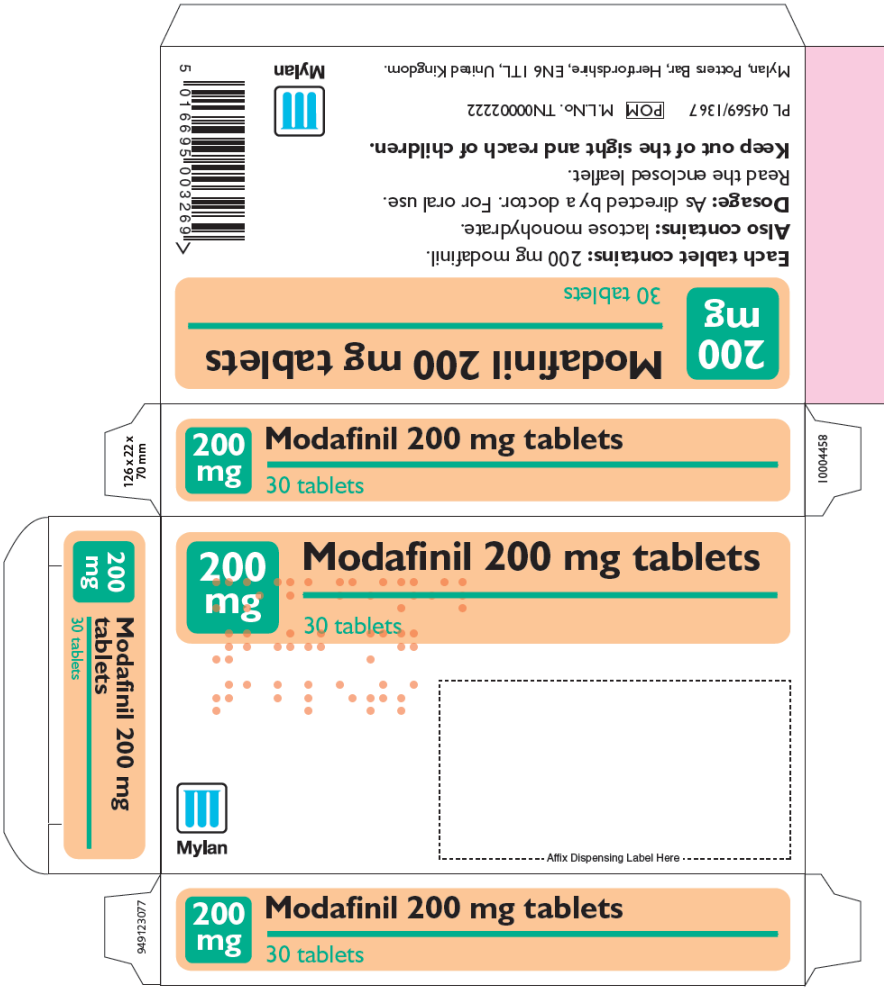
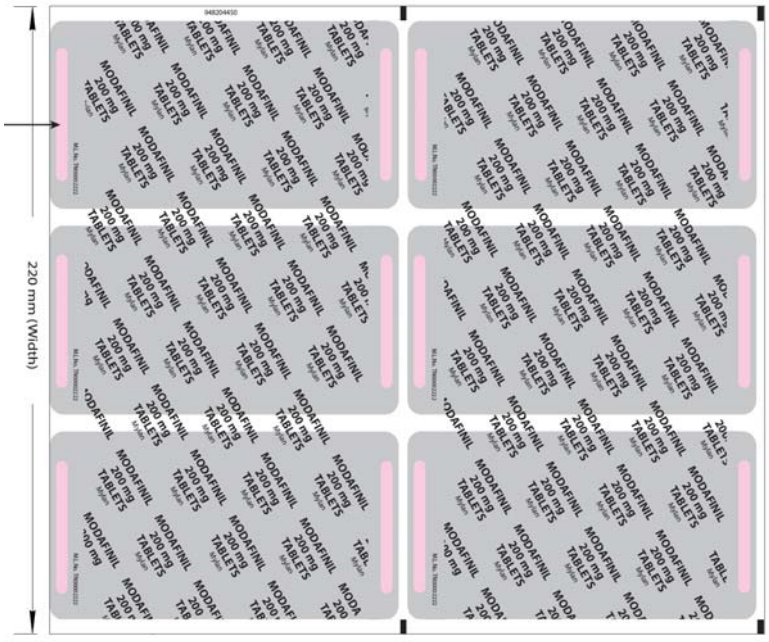
## Summary of Product Characteristics and Patient Information Leaflet

In accordance with Directive 2012/84/EU, the current approved UK versions of the Summaries of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for this product is available on the MHRA website.

# Labelling


Modafinil 200 mg tablets
30 tablets
200 mg
Each tablet contains: 200 mg modafinil.
Also contains: lactose monohydrate.
Dosage: As directed by a doctor. For oral use.
Read the enclosed leaflet.
Keep out of the sight and reach of children.
PL 04569/1367 POM M.L.No. TN00002222
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.
Mylan
126 x 22 x 70 mm
10004458
Affix Dispensing Label Here
949123077


220 mm (Width)