

This shared care protocol (SCP) sets out details for the sharing of care for patients prescribed Modafinil for the treatment of Narcolepsy. It should be read in conjunction with the latest [Summary of Product Characteristics](#) (SPC)

As outlined in NHS Circular 1992 (Gen 11), when a consultant considers a patients' condition is stable he/she may seek the agreement of the patients' GP to "share" the patients' care. This document provides information on drug treatment for the shared commitment between the consultant and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Introduction

Modafinil is a centrally acting sympathomimetic; its precise mechanism which promotes wakefulness is unknown. It does not appear to be a direct or indirect α_1 adrenoreceptor or dopamine receptor agonist. Modafinil is known to selectively and prominently increase neuronal activation in discrete regions of the brain, particularly the hypothalamus. The level and duration of wakefulness and daytime alertness is restored and/or improved in a dose-related manner.

For further information please click on the links below or visit;

[British National Formulary](#)
[Summary of Product Characteristics](#)

Licensed Indications

Modafinil is indicated in adults (>18years) for the treatment of 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.

Dose (posology & method of administration) (click for details in SPC)

- The recommended starting daily dose in adult patients is 200 mg. The total daily dose may be taken as a single dose in the morning or as two doses in the morning and at noon according to physician assessment of the patient and the patient's response.
- Doses of up to 400mg in one or two divided doses can be used in adult patients with insufficient response to the initial 200mg modafinil dose.
- Refer to SPC with regard to elderly patients and those patients with renal or hepatic impairment.

[Contra-indications](#) (click for details in SPC)

- Hypersensitivity to the active substance or to any of the excipients.
- Uncontrolled moderate to severe hypertension and in patients with cardiac arrhythmias.

[Special warnings and precautions for use](#) (click for details in SPC)

- **An ECG is recommended in all patients before Modafinil treatment is initiated. Patients with abnormal findings should receive further specialist evaluation and treatment before modafinil treatment is considered.** Blood pressure and heart rate should be regularly monitored in patients receiving modafinil. Modafinil should be discontinued in patients who develop arrhythmia or moderate to severe hypertension and not restarted until the condition has been adequately evaluated and treated. Modafinil tablets are not recommended in patients with a history of left ventricular hypertrophy or cor pulmonale and in patients with mitral valve prolapse who have experienced the mitral valve prolapse syndrome when previously receiving CNS stimulants. This syndrome may present with ischaemic ECG changes, chest pain or arrhythmia.
- **Patients should be monitored for the development of de novo or exacerbation of pre-existing psychiatric disorders at every adjustment of dose and then regularly during treatment.** If psychiatric symptoms develop in association with modafinil treatment, modafinil should be discontinued and not restarted.
- **Caution should be exercised in giving modafinil to patients with a history of psychiatric disorders.** These include psychosis, depression, mania, major anxiety, agitation, insomnia or substance abuse.
- **Modafinil should be discontinued at the first sign of rash and not re-started.** Serious rash requiring hospitalisation and discontinuation of treatment has been reported. Cases of serious or life-threatening rash, including Stevens - Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) have been reported.
- **Contraception:** Sexually active women of child-bearing potential should be established on a contraceptive programme before taking modafinil. Since the effectiveness of steroidal contraceptives may be reduced when used with modafinil, alternative or concomitant methods of contraception are recommended, and for two months after discontinuation of modafinil

[Interactions](#) (click for details in SPC)

[Pregnancy and Lactation](#) (click for details in SPC)

[Adverse effects](#) (click for details in SPC)

[Effects on ability to drive](#) (click for details in SPC)

Patients with excessive sleepiness, including those taking modafinil should be frequently reassessed for their degree of sleepiness and, if appropriate, advised to avoid driving or any other potentially dangerous activity. Undesirable effects such as blurred vision or dizziness might also affect ability to drive.

Shared Care Responsibilities

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to, and accepted by, the patient. This provides an opportunity to discuss drug therapy.

The standards have been agreed for the monitoring of modafinil therapy in patients with narcolepsy across the Somerset Healthcare Community.

The clinician who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Specialist responsibilities:-

1. Do cardiac checks: ECG, BP and heart rate before commencing treatment.
2. Do baseline monitoring of clinical parameters.
3. Discuss the risks and benefits of medication with patients and carers.
4. Sexually active women of child bearing potential should be established on a suitable contraceptive.
5. Prescribe until a maintenance regimen is established.
6. Communicate to the GP: diagnosis, treatment regimen, monitoring requirements and criteria for referral.
7. Review the patient at least once a year (more frequently if clinically indicated).
8. Advise the GP on review, duration or discontinuation of treatment, where necessary.
9. Inform the GP of patients who do not attend clinic appointments.
10. Inform the GP, by letter, of clinic visits and action taken for management of the patient.
11. Advise the GP regarding any concerns about monitoring or adverse effects at any stage.
12. Ensure that backup advice is available at all times.

Consultant monitoring

- **ECG before starting treatment**
- **BP and heart rate**

Check for arrhythmia or moderate to severe hypertension. If present – stop treatment – refer to consultant

- **Monitor for potential adverse effects and special precautions and warnings that may apply**

General Practitioner responsibilities:-

1. Continue discussion of risks and benefits with patients and carers, as required.
2. Prescribe as soon as the maintenance dose is established.
3. Be aware of potential drug interactions.
4. Continue monitoring as agreed with secondary care and refer back if clinically indicated.
5. Review the patient every 6 months (more frequently if clinically indicated).
6. Respond to and report any adverse events to the consultant.

General Practitioner monitoring

- **BP and heart rate**

Check for arrhythmia or moderate to severe hypertension. If present – stop treatment – refer to consultant

- **Monitor for potential adverse effects and special precautions and warnings that may apply**

If a rash occurs – stop treatment and refer to consultant.

If psychiatric symptoms occur - stop treatment and refer to consultant.

Patient/carer responsibilities

1. Report to the GP or specialist if there is not a clear understanding of the treatment.
2. Attend all clinic and GP appointments.
3. Report any adverse effects to their GP and/or specialist whilst on treatment.
4. Report any changes in symptoms to the GP or specialist whilst taking whilst on treatment.
5. Alert the GP and/or specialist to any changes which could affect treatment e.g. pregnancy.

Drug cost

Drug Tariff, April, 2014

Modafinil tablets 100mg, 30 tablets: £15.51

Modafinil tablets 200mg, 30 tablets: £78.75 (do not use as relatively high cost).

Formulation	Dose	Cost for 30 days
100mg tablets	200mg daily	£31.02
	300mg daily	£46.53
	400mg daily	£62.04

Further support

- Medicines Information department, Musgrove Park Hospital: 01823 342253
- Medicines Information department, Yeovil District Hospital: 01935 384327
- Prescribing & Medicines Management Team, NHS Somerset: 01935 384123

Version:	2.1	Date
Drawn up by:	Version 2.0 by Nigel Ankcorn, Lead Pharmacist, MI, Musgrove Park Hospital	April, 2014
Approved by:	Somerset Prescribing Forum, NHS Somerset	
	Drug & Therapeutics Committee, Taunton & Somerset NHS FT	
	Drug & Therapeutics Committee, East Somerset NHS FT	
	Drug & Therapeutics Committee, Somerset Partnership NHS FT	
	Version 2.1 Shared Care Guideline version 2.0 put into Somerset CCG shared care template by Helen Kennedy, Prescribing Support Technician, Somerset CCG	9 th April 2014
Review required by:		April 2017

References

- [Summary of product characteristics: modafinil 100mg tablets](#); Genus Pharmaceuticals; last updated on the eMC: 03/03/2014 SPC Modafinil 100mg Tablets
- [British National Formulary online](#) [accessed 27/03/2014 14:50]
- [Modafinil \(Provigil\): information to support safer use; now restricted to narcolepsy](#). MHRA Drug safety update, March, 2011.