Modafinil

Shared Care Guidelines

Specialist Details	Patient Details
Name: _____ Location: _____ Tel: _____	

Diagnosis:

Introduction

Modafinil is not a typical stimulant and is not chemically related to amphetamines. It appears to work by increasing the signalling effect of dopamine and noradrenaline in the brain. It is often described as a "wakefulness promoting agent" and has been classed as a memory-improving and mood-brightening psycho stimulant. It is usually well tolerated.

Modafinil is licensed for the treatment of daytime sleepiness associated with narcolepsy and more commonly used for idiopathic daytime hypersomnolence syndrome and some muscle dystrophies.

Modafinil should not be used in patients with uncontrolled hypertension, cardiac arrhythmias or in women who are pregnant or breastfeeding.

Modafinil should be discontinued and not restarted in cases of: serious skin or hypersensitivity reactions or psychiatric disorders such as suicidal ideation.

The licensed dose is 200mg per day, which may be increased up to 400mg per day if necessary. In exceptional circumstances, doses more than 400mgs per day are used. The total daily dose can be divided over two doses throughout the day. This can maintain effectiveness and reduce the incidence of side effects. However, the second dose should not be taken so late that it impacts upon normal planned sleep.
The starting dose in sleep medicine is usually 100mg twice daily at 08:00hrs and then no later than 14:00hrs.

Specialist Responsibilities	• Initiation of prescription of modafinil for a one-month trial. • Titration of modafinil dose to the optimum level for control of symptoms (the dose must be stabilised) before transferring to the GP • Monitoring for response and adverse drug reactions (ADRs) during the initiation period. • Ask the general practitioner (GP), using this Shared Care Request Form, to share the patient's care when a stable dose has been achieved and proven benefit has been established. • Evaluating ADRs raised by the GP and evaluating any concerns arising from physical checks and reviews undertaken by GP. • The patient must be reviewed approximately every 6 months by the specialist <u>Monitoring</u> • A baseline electrocardiogram should be done before treatment initiation. Patients with abnormal findings should be further evaluated by specialists before modafinil treatment can be initiated
GP Responsibilities	• Reply to request for shared-care as soon as practical (within 28 days). • Prescribe modafinil in accordance with the specialist's recommendations. • Stop or adjust treatment on advice of, or in consultation with, a specialist. • To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment. • Report adverse events to specialist and MHRA. <u>Monitoring</u> • Cardiovascular function – especially blood pressure and heart rate – should be monitored every 6 months. Modafinil should be discontinued in patients who develop arrhythmia or moderate to severe hypertension, and should not be restarted until the condition has been adequately evaluated and treated. However it is recommended that raised BP or heart rate should be discussed with the specialist before taking action. o Note: taking the drug away abruptly will lead to a return of the Excess Daytime Hypersomnolence within a day or two affecting the person's ability to work and drive.

Adverse Effects, Precautions and Contraindications

Contra-indications

- Pregnancy and lactation, due to a lack of specific information on safety.
- Uncontrolled moderate severe hypertension, left ventricular hypertrophy, cor pulmonale.
- Hypersensitivity to modafinil or any components of the preparation.
- Modafinil tablets contain lactose and should not be used in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency on glucose and galactose malabsorption.

Hepatic & Renal Impairment

Dose should be halved in sever hepatic impairment.
Safety in renal impairment has not been adequately assessed.

Caution: 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

Adverse Effect Monitoring

The MHRA has advised that modafinil should be withdrawn in patients who experience a rash or psychiatric symptoms, and makes the following recommendations :

- Modafinil should be discontinued at the first sign of rash and not restarted
- Modafinil should be discontinued in patients who experience any psychiatric symptoms and not restarted

Additionally:

- Modafinil should be used with caution in patients with a history of psychosis, depression, or mania
- Modafinil should be used with caution in patients with a history of alcohol, drug, or illicit substance abuse
- Such patients should be monitored closely and advised to report any suspected adverse behaviours or thoughts. Patients should be assessed immediately and treatment stopped if appropriate

Modafinil has a low potential for dependence, but the possibility of dependence over the long-term cannot be excluded.

***Driving* -** The effect of Modafinil on driving has not been specifically studied. Patients should be advised that they must not drive if they experience undesirable effects such as blurred vision or dizziness that affect their ability to drive safely.

Monitoring: Blood pressure and heart rate should be monitored in hypertensive patients – these should be checked when the specialist assesses the efficacy of modafinil. In patients on long-term treatment, monitoring should be carried out as part of the routine management of the patient's hypertension.

Side-effects: Headache is the most common mental adverse effect affecting about 21% of patients. This is usually mild or moderate and disappears after a few days.

See the manufacturers' summary of product characteristics (SPC) for a comprehensive list of other adverse effects

Common Drug interactions	***Ciclosporin*** – Modafinil accelerates the metabolism of ciclosporin and reduces plasma levels. Adjustment of dose may be required. ***Contraceptives -*** Modafinil accelerates the metabolism of oestrogens and may reduce their contraceptive effect. Alternative or concomitant contraceptive measures should be used during treatment with modafinil and for two months after stopping. ***Phenytoin*** - Modafinil may increase phenytoin levels – monitor patients on phenytoin for signs of toxicity. Measurement of plasma phenytoin levels may be appropriate on initiation and discontinuation of modafinil. ***Warfarin*** - Modafinil may reduce the clearance of warfarin. Patients should be monitored regularly during the first two months of treatment with modafinil and after each change in dose.
Communication	**Specialist to GP** • Obtaining agreement of GP to participate in shared-care arrangement for modafinil therapy (by sending a copy of this document). • Prompt communication with the GP regarding the patient's progress, any reassessment and changes in treatment. • Provide additional information and advice to the GP on actions he/she may need to take e.g. on dosage adjustment, other changes in therapy and management of adverse effects, as required. **GP to Specialist** • Reply to request for shared-care as soon as practical (within 28 days). • To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment. **Contact names and details** If you have any concerns regarding an individual patient, contact the Specialist or secretary. *Details* **This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the BNF or SPC for further prescribing information**