HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Modafinil for Daytime Hypersomnolence

Patients Name:…… Unit Number: ……

Patients Address:……(Use addressograph sticker)

G.P's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:…….

Where prescriber is <u>not</u> a consultant:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……..... ……. Date:…….

GP's Signature:…… Date:……..

GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.
The patient's GP should sign and send back to specialist, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **<u>unwilling</u>** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at: http://www.hey.nhs.uk/amber.htm

1. Background

Modafinil is a non-amphetamine central nervous system stimulant which improves the level and duration of wakefulness and daytime alertness. It is licensed for treatment of daytime hypersomnolence associated with narcolepsy with or without sleep apnoea.

These guidelines aim to provide clinicians in primary care with relevant information when prescribing modafinil.

The guidelines should be read in conjunction with the general guidance on prescribing matters given in EL (91) 127 “Responsibility for prescribing between hospitals and GPs”.

2. Indication

Idiopathic daytime hypersomnolence with narcolepsy with or without cataplexy.
Unlicensed indications remain RED.

3. Dose

Initially 100mg daily increased to 400mg daily, as advised by specialist.

Can be taken as single daily dose or more commonly taken in 2 divided doses, in the morning and at noon.

(Dose should be halved in patients with severe renal or hepatic impairment.)

4. Duration of treatment

May be long term depending on patient response.

5. Contraindications and cautions

Modafinil is contraindicated in patients with uncontrolled moderate to severe hypertension, or arrhythmia, history of left ventricular hypertrophy, cor pulmonale, or of clinically significant signs of CNS stimulant-induced mitral valve prolapse (including ischaemic ECG changes, chest pain and arrhythmias).
Also contraindicated during pregnancy and lactation.

Use with caution in patients with history of psychosis, anxiety, depression, mania, bipolar disorder, alcohol or drug abuse. Discontinue treatment if psychiatric symptoms develop, possibility of dependence or if rash develops.

6. Adverse effects

Most commonly reported (> 1 in 10) side effect is headache.
Other side effects reported ($\geq$1/100 to $\leq$1/10,) include dizziness, somnolence, paraesthesia, blurred vision, tachycardia, palpitation, abdominal pain, nausea, dry mouth, diarrhoea, dyspepsia, constipation, decreased appetite, vasodilatation, asthenia, chest pain, nervousness, insomnia, anxiety, depression, abnormal thinking, confusion, irritability.

Dose related increases in alkaline phosphatase and gamma glutamyl transferase have been observed.

For complete list always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

7. Interactions

The effectiveness of combined and progestogen only contraceptives may be reduced when used with modafinil. Alternative or concomitant methods of contraception are recommended, and for two months after discontinuation of modafinil.

For complete list always check with BNF or Data Sheet (available electronically at www.medicines.org.uk)

8. Monitoring

ECG is required prior to initiation.

Blood pressure and heart rate should be monitored regularly as advised by specialist (at least every 3 months).

Clinical response and adverse effects will be monitored by specialist and general practitioner.

9. Information to patient

Patient should be advised of risks and benefits of treatment. (where relevant, patients should be warned that side effects may impair ability to drive, operate machinery)

10. Responsibilities of clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	Select patients appropriate for treatment. Inform patient of risks and benefits of treatment and supply arrangements. Arrange for baseline ECG. Prescribe and assess patient's response until dose stabilised. Contact the GP to invite shared care for the patient and provide information on treatment.	
Maintenance	Assess clinical response to treatment Provide adequate advice and support to GPs Inform GP of dose amendments if appropriate	Prescribe treatment once stabilised. Monitor patient for efficacy. Monitor for adverse effects. Refer to specialist where appropriate Check BP 3/12

Contact Details:

During office hours:

Neurology specialist pharmacist

Jane Morgan (01482) 674411

Consultant neurologist

As per clinic letter Via switchboard

Out of hours: contact on call registrar for neurology via switchboard

APPROVAL PROCESS for Shared Care Framework

Written by:	**Marie Miller, Interface Pharmacist** **Reviewed Jane Morgan, Neurology Specialist Pharmacist, Dec 2013, Reviewed: Jane Morgan, Neurology Specialist Pharmacist, November 2017**
Consultation process:	**Dr A Ming, Consultant Neurologist**
Approved by:	**Medicines Management Interface Group (June 2010)**
Ratified by:	***HERPC Jan 2014***
Review date:	***November 2020***