South Tees Clinical Commissioning Group

Shared care guidelines

Drug	MODAFINIL (PROVIGIL® ▼)		
Specialty	NEUROLOGY		
Indication	EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY (in adults only)		
Overview	Modafinil appears to act specifically on "wake centres" in the brain and is not a typical psycho-stimulant. Treatment should be initiated by a physician with appropriate knowledge of relevant sleep disorders. Where appropriate, every effort should be made to assess and treat other potential causes of sleepiness in narcolepsy (e.g. sleep apnoea), prior to initiating treatment with Modafinil		
Hospital specialist's	Initial investigations:	Assessment for contraception, pregnancy, breast-feeding, heart disease, psychiatric illness, substance misuse/drug diversion as appropriate. ECG, BP, pulse, renal & hepatic function	
responsibilities	Contra-indications:	Uncontrolled hypertension, cardiac arrhythmia, pregnancy, breast-feeding	
	Caution:	Under 18yr	
	Initial regimen:	Adult 18-65 years: 200mg daily, as a single dose in the morning or as two divided doses in the morning and at lunchtime; titrated according to clinical response to 200-400mg daily (100mg-200mg daily if severe renal/hepatic impairment)	
	Clinical monitoring:	For effectiveness – ideally before transfer to GP; discontinue if not effective	
	Safety monitoring:	BP & pulse – after each dose change, and at every review Weight – at every review	
	Review:	Usually 6 monthly	
	Prescribing arrangements: Initiated by specialist. Transferred to GP once efficacy established and dose stabilised (minimum 1 month after initiation)		
	Documentation : Clinic letters to GP, copied to patient/carer – to include treatment changes a notification of DNA.		
GP's responsibilities	Maintenance prescription: Adult 18-65 years: 200-400mg daily (100mg-200mg daily if severe renal/hepatic function), as advised by hospital specialist		
responsibilities	Clinical monitoring:	Routine care, as required	
	Safety monitoring:	BP & pulse - initially monthly until dose stabilised, then every 6 months Weight – annually LFTs – if any signs/symptoms of abnormality	
	Duration of treatment		
	Documentation:	Record prescribing & monitoring in clinical records	

Adverse events

Adverse Event	Action (notify specialist of all side effects)
Raised BP or pulse	Refer to specialist
Weight increase / decrease	Refer to specialist
Signs / symptoms of heart disease	Refer to specialist
Abnormal LFTs	Refer to specialist
Psychiatric disorders, e.g. suicidal ideation	Discontinue & refer to physician
Serious skin or hypersensitivity reactions	Discontinue & refer to physician

Other information

Modafinil is no longer licensed for the treatment of excessive sleepiness associated with obstructive sleep apnoea/hypopnoea syndrome (OSAHS) or chronic shift work sleep disorder (SWSD), and shared care does not apply to these conditions.

Modafinil is a mild hepatic enzyme inducer and potential drug interactions can occur. Particular care is needed when considering oral contraception.

Care is needed in patients with heart disease or hypertension although the effects on systolic blood pressure are minimal (mean increase of 2 mmHg).

▼ This drug is monitored intensively by the CHM and MHRA – report all side-effects via yellow card scheme (http://yellowcard.mhra.gov.uk/)

Specialist contact details

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