

North of Tyne, Gateshead and North Cumbria Area Prescribing Committee

Methylphenidate

Shared Care Guidance

For the Management of Narcolepsy in Adults and Children

Formulary Traffic Light Classification – Amber

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| Introduction | |
| Indication An “off- label” but routine treatment option for Narcolepsy within a specialist sleep clinic. | |
| Background Methylphenidate is used as a second line agent when modafinil is not effective or tolerated. Methylphenidate is initiated in secondary care by a specialist. Treatment may be continued and monitored by a general practitioner under a shared-care arrangement. The need to continue Methylphenidate therapy should be reviewed by specialist every 6-12 months. | |
| Dose and Administration (for full details see SPC and BNF/BNFc) | |
| Formulary preparation | Prolonged Modified Release Tablets - 18mg, 27mg, 36mg and 54mg tablets (Please prescribe by brand name) Xaggitin® XL is the current preferred brand by the North of Tyne, Gateshead and North Cumbria Area Prescribing Committee Note: Xaggitin® XL is bioequivalent to Concerta® XL |
| Dosing | Adults: initially 18mg each morning In the absence of improvement after 2 weeks the dose can be increased to 36mg and then review by specialist to consider if further titration is appropriate. Dose range: 18mg to Maximum of 72mg. Treatment should be stopped in those that fail to demonstrate a response to the maximum dose. Children: see SPC |
| Common adverse effects - See SPC and BNF/BNFC for full details | |
| Methylphenidate is typically well tolerated at lower doses with effective and sustained benefit on alertness. <ul style="list-style-type: none"> Decreased appetite, weight loss, growth retardation, insomnia, mood changes, headache, dizziness, drowsiness, tachycardia, increased blood pressure, cough, gastrointestinal side effects, rashes, mood swings, delusions, hallucinations, anxiety, panic, stimulant related tics, sexual dysfunction. | |
| Potentially Serious drug interactions -- See SPC and BNF/BNFC for full details | |
| <ul style="list-style-type: none"> Enhance anticoagulant effect of warfarin- monitor INR May inhibit the metabolism of anticonvulsants (e.g. phenobarbital, phenytoin, primidone), and some antidepressants (tricyclics and selective serotonin reuptake inhibitors) resulting in increased plasma levels and possible enhanced effect - monitor Can exacerbate CNS adverse effects of alcohol -abstention advised | |

- Monoamine oxidase inhibitors (MAOIs) – methylphenidate should not be taken either with or within 14 days of an MAOI. Potential risk to precipitate hypertensive crisis
- Serotonergic products – monitor and discontinue if serotonin syndrome is suspected.
- May decrease the effectiveness of drugs used to treat hypertension - monitor blood pressure
- May oppose the effects of beta blockers - monitor blood pressure and heart rate

Contraindications/Cautions

- Known intolerance of sympathomimetic amines
- Hypersensitivity to the active substance or to any of the excipients
- Marked anxiety, agitation, tension or psychosis - poorly controlled
- Bipolar Affective Disorder or psychopathic/borderline personality disorder
- Severe depression, anorexia/anorexic disorders,
- Suicidal ideation,
- History of drug or alcohol abuse
- Glaucoma
- Hyperthyroidism or thyrotoxicosis
- Cardiac abnormalities
- Current or recent (within 14 days) treatment with MAOI's
- Some cardiovascular disease - including severe hypertension
- Motor tics, or family history of Tourette's syndrome
- Pheocromocytoma
- Use with caution in:
 - Epilepsy, stimulants may lower the seizure threshold in patients with a prior history of seizures. If seizure frequency increases, the specialist should discontinue methylphenidate
 - Or where there is a history of severe and episodic Bipolar (Affective) disorder that is not well controlled
 - Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine
 - Caution is advised in patients on any other drug that can also elevate blood pressure

Specialist responsibilities

- Assessing suitability of patients for treatment and confirmation of diagnosis of narcolepsy, hypersomnia
- Discuss the treatment options with the patient, their parent(s) and carer(s) where relevant, to include explanation of unlicensed use, potential side effects and potential for dependency.
- Initiate and supply medication for first 6 weeks as a minimum or until the dose is stabilized.
- Supply one month's Methylphenidate after dose has been stabilised to ensure continuity of supply while arranging shared care.
- Arrange shared care with patient's GP
- Assess and monitor patients' response to treatment and the need to continue therapy on a 6-12 monthly basis.
- Monitor – blood pressure, heart rate, weight and any psychological effects on behavior.
- Provide the GP with relevant information for each patient including treatment to be undertaken by GP
- Report any suspected ADRs to CSM via Yellow Card system.

- Discontinuation – advise discontinuation if no improvement in symptoms seen after a reasonable trial of up to three months or if adverse effects or dependency advising GPs when and how a trial withdrawal of Methylphenidate should be undertaken
- Provide GP with any further advice if required

GP Responsibilities

- Prescribe Methylphenidate
- Report any adverse effects to specialist and regulatory bodies i.e. CSM via Yellow Card process.
- Liaison with consultant regarding any complications of treatment.
- Ask the specialist to take back the prescribing should unmanageable problems arise.
- It is anticipated that most of the patients will have monitoring conducted at sleep clinic. GP may be asked to assist with monitoring blood pressure, heart rate and weight where patients have difficulty attending the hospital.

Communication/Contact Details

Specialists Mon – Fri 09:00 – 17:00

- Newcastle regional sleep service via switchboard 0191 233 6161

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF

Approved: March 2023

Review: March 2026

Private and Confidential

Methylphenidate for Narcolepsy in Adults and Children - Shared Care Request/Confirmation

- Specialist Prescriber to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 days
- A copy of the full shared care guideline can be viewed at www.northoftyneapc.nhs.uk

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|--|----------------------|------------|--|
| Specialist Prescriber | | | |
| Department | | | |
| Hospital | | | |
| Telephone | | | |
| Patient details (use hospital label if preferred) | | | |
| Name | | | |
| Address | | | |
| Postcode | | | |
| NHS or Hosp reg no | Male / Female | DoB | |

| Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement | | | | | |
|--|---------------------|-------------|--|------------------|--|
| Drug Information | | | | | |
| Name/Formulation | | Dose | | Frequency | |
| Name/Formulation | | Dose | | Frequency | |
| Name/Formulation | | Dose | | Frequency | |
| Indication -Adult ADHD | | | | | |
| Other information (if appropriate) | | | | | |
| | | | | | |
| Signed (Specialist Prescriber) | Name (Print) | Date | | | |

| To be completed by GP | | Please tick one box |
|--|---------------------|--------------------------|
| I ACCEPT the proposed shared care arrangement for this patient | | <input type="checkbox"/> |
| I ACCEPT the proposed shared care arrangement with the caveats below | | <input type="checkbox"/> |
| I DO NOT ACCEPT the proposed shared care arrangement for this patient | | <input type="checkbox"/> |
| My caveats/reason(s) for not accepting include: | | |
| | | |
| Signed | Name (print) | Date |