Children and Young People ADHD - Methylphenidate Shared Care Protocol		
V1.3	Last reviewed: January 2024	Review date: January 2027

NHS
Nottinghamshire Area Prescribing Committee

Methylphenidate in children and young people services

Adapted from local adult ADHD shared care protocol which is based on the national adult template published by NHS England .

Traffic light classification- AMBER 1

The content of this shared care protocol was correct as of January 2024. Please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Children and Young People ADHD - Methylphenidate Shared Care Protocol		
V1.3	Last reviewed: January 2024	Review date: January 2027

NHS
Nottinghamshire Area Prescribing Committee

Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, write to the patient's GP practice detailing the diagnosis, brand to be prescribed, current and ongoing dose, any relevant test results and when the next monitoring is required. Include specialist service contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations should be managed by the specialist.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- If shared care is not accepted, inform the specialist of the decision in writing within 14 days with reasons as to why shared care cannot be entered into. If shared care is accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, taking into account any potential drug interactions in section 7.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Adjust the dose of methylphenidate prescribed as advised by the specialist, in line with section 5. See section 5 for further details regarding responsibility for dose and formulation changes.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for possible interactions with methylphenidate when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop methylphenidate and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected. See section 10
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.
- Ensure the patient is given the appropriate appointments for monitoring. If a patient fails to attend, contact the patient in a timely manner and arrange an alternative appointment.

Patient and/or carer responsibilities

- Take methylphenidate as prescribed, and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications (OTC) to their primary care prescriber and be aware they should discuss the use of methylphenidate with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if methylphenidate affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 11).
- Avoid alcohol during treatment, as it may make some side effects worse. Avoid recreational drugs.

- Methylphenidate is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store methylphenidate safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

Back to top

Methylphenidate is a central nervous system stimulant licensed as part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD). The precise mechanism of action by which it works on ADHD is unknown. It may be offered as a first line pharmacological treatment option for children aged 6 and overwith ADHD who have been appropriately diagnosed. Treatment must be initiated under the supervision of a specialist in childhood behaviour disorders. It is usually used for ADHD where there is no significant co-morbidity or for ADHD with co-morbid oppositional defiant disorder (ODD) or conduct disorder. NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management).

Whilst NICE guidance state that medication can be prescribed from the age of 5, this is unlicensed and done with caution in exceptional circumstances by specialists therefore children < 6 years old are excluded from this shared care protocol. Patients ≥ 18 years old are covered by a separate shared care protocol.

Methylphenidate is available as immediate-release tablets, and modified-release tablets and capsules. The modified-release preparations contain both immediate-release and prolonged-release methylphenidate, and different brands have different proportions of each. Brands may therefore vary in their release characteristics and clinical effect. Modified-released preparations should therefore be prescribed by brand name.MHRA September 2022 drug safety warning : Caution if switching patients between different long acting formulations of methylphenidate. Please see the preferred prescribing list for Nottinghamshire. However, during periods of drug shortages please refer to the APC ADHD shortages page and or Nottinghamshire Joint Formulary for local guidance and support tools.

Methylphenidate is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance NG46 Controlled drugs: safe use and management. Risk of misuse can be reduced by using modified-release preparations.
Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) or Community Paediatric team but is approaching their 18th birthday, it is expected that CAMHS

or Community Paediatric team will refer to the appropriate adult service if need for ongoing treatment is anticipated. See the Nottinghamshire Area Prescribing Committee shared care protocol and medication information leaflets for adult ADHD at:

https://www.nottsapc.nhs.uk/shared-care/.
The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials. Patients should be reviewed for ongoing need at least annually, and the manufacturers recommend a trial discontinuation at least once yearly to assess the patient's condition.

2. Indications

Back to top

Attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over
) Whilst NICE guidance state that medication can be prescribed from the age of 5, this is unlicensed and done with caution in exceptional circumstances by specialists therefore children < 6 years old are excluded from this shared care protocol. Patients ≥ 18 years old are covered by a separate shared care protocol.

3. Locally agreed off-label use

Back to top

None

4. Contraindications and cautions

Back to top

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Hypersensitivity to methylphenidate or to any of the excipients or sympathomimetic amines
- Glaucoma
- Phaeochromocytoma
- During treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days of discontinuing those drugs, due to the risk of hypertensive crisis
- Hyperthyroidism or thyrotoxicosis
- Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies (consult specialist), psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder.

- Diagnosis or history of severe and episodic (Type I) bipolar (affective) disorder (that is not well-controlled).
- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, and structural cardiac abnormalities.
- Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke.
- Medikinet XL only: history of pronounced anacidity of the stomach with a pH value above 5.5, or during therapy with H2 receptor blockers, proton pump inhibitors or antacids.

Cautions:

- Family history of sudden cardiac or unexplained death, malignant arrhythmia.
- Cardiovascular status should be carefully monitored (see section 9 & section 10)
- Sudden death has been reported in association with the use of stimulants of the central nervous system at usual doses in patients, some of whom had structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone may carry an increased risk of sudden death, stimulant products are not recommended in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant medicine
- Underlying conditions which might be compromised by increases in blood pressure or heart rate.
- Known drug or alcohol dependency or misuse of central nervous system (CNS) stimulants: potential for abuse, misuse or diversion.
- Alcohol consumption (not recommended during treatment)
- Epilepsy: may lower seizure threshold
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, depressive symptoms, bipolar disorder.
- Renal or hepatic insufficiency (due to lack of data)
- Leukopenia, thrombocytopenia, anaemia, or other haematological abnormalities.
- Prolonged-release tablets only: severe narrowing of the gastrointestinal tract or dysphagia; risk of obstruction
- Safety and efficacy has not been established in patients older than 60 years of age.
- Susceptibility to open-angle glaucoma.
- Pregnancy or breast-feeding (see section 12)
- Potential for abuse, misuse, or diversion.

5. Initiation and ongoing dose regimen

Back to top

- Transfer of monitoring and prescribing to primary care is normally after at least 4weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Further details about primary care monitoring requirements are detailed in section 9.
- Termination of treatment will be the responsibility of the specialist unless in the case of managing adverse effects as detailed in section 10

Dose Adjustments

- For patients already receiving prescriptions under shared care, when a specialist adjusts the dose, the specialist retains responsibility for prescribing and for determining tolerance and clinical stability during the initial period following the change.
- Prescribing within primary care may be requested after a minimum of four weeks, once the specialist has determined that the patient has demonstrated tolerance and clinical stability with the new dose.
- Once stability is confirmed, the specialist should write to the patient's GP practice confirming the dose change, preparation/brand where appropriate, ongoing dose, relevant test results, and when the next monitoring is required, and request the GP to resume prescribing. Specialist contact details should be included. The specialist should prescribe sufficient medication (normally a 28-day supply) to support continuation of prescribing in primary care, including where there are unforeseen delays.
- Where clinically appropriate and judged to be in the patient's best interests, and following clearly documented discussion and agreement between the specialist and the primary care clinician, prescribing at the adjusted dose may be undertaken in primary care. Responsibility for determining tolerance and clinical stability following the dose change remains with the specialist. Monitoring should be undertaken in line with specialist advice as outlined in section 9.

Formulation Changes

- For patients already receiving prescriptions under shared care, when a specialist alters the formulation of medication, the specialist retains responsibility for prescribing and for determining tolerance and clinical stability during the initial period following the change.
- Prescribing within primary care may be requested after a minimum of four weeks, once the specialist has determined that the patient has demonstrated tolerance and clinical stability with the new formulation.

- Once stability is confirmed, the specialist should write to the GP practice confirming the formulation change, preparation/brand where appropriate, ongoing dose, relevant test results, and when the next monitoring is required, and request the GP to resume prescribing. The specialist should prescribe sufficient medication (normally a 28-day supply) to support continuation of prescribing in primary care.

Recommended dosage in ADHD:

The immediate-release methylphenidate formulation may be used, but simple medication regimens are often preferred (e.g. once daily morning dose of a modified-release preparation).

Immediate release tablets: Ritalin® / Tranquilyn® / Medikinet® / generic immediate-release preparations

- 5 mg once or twice daily (e.g morning and noon(which can be increased at weekly intervals by 5-10mg, up to 60mg daily in 2-3 divided doses (morning, noon and afternoon). Increasing the total daily dose of immediate-release methylphenidate to 2.1mg/kg/day (max. 90mg/day (adolescents) may occasionally be undertaken by a specialist in cases of poor response to medication treatment.
- Doses of immediate release methylphenidate above 60mg/day (or equivalent dose of modified or prolonged release preparations. Check individual SPC for equivalent doses) are unlicensed and patients should be closely monitored for side-effects during the titration period.

- **Prolonged release tablets (12 hour preparation): Affenid ®XL / Atenza ®XL / Concerta® XL Delmosart / Matoride XL / Xaggitin XL/ Xenidate XL:** Prolonged-release form of methylphenidate (22% IR / 78% PR) administered once daily in the morning, formulated to replace three times daily dosing with the immediate-release formulation. Prolonged release tablets have longest duration of the modified-release preparations lasting between 8 to 12 hours. The dose may be adjusted in 9mg or 18 mg increments, from an initial dose of 18mg once daily (equivalent to 15mg daily immediate release), to a maximum of 54 mg/day at approximately weekly intervals. Although 54mg/day is the maximum licensed dose (equivalent to 45mg/day of immediate release methylphenidate), the dose may be increased up to 2.1mg/kg daily (max. 108mg/day) under the direction of a specialist.

Modified release capsules (8 hour preparation):

Equasym XL® is a modified-release form of methylphenidate (30% IR / 70% PR) administered once daily in the morning, formulated to be similar to twice daily dosing with the immediate-release formulation. A single dose of Equasym XL typically lasts between 6 to 10 hours. The dose may be adjusted in 10mg increments at weekly intervals to a maximum of 60mg/day. Although 60mg/day is the maximum licensed dose, the dose may be increased up to 2.1mg/kg daily (max. 90mg/day) under the direction of a specialist.

Focusim XL®/ Medikinet XL®/Meflynate XL® / Metyrol XL ®/ Ritalin XL®capsules - modified-release forms of methylphenidate (50% IR / 50% PR) administered once daily in the morning, formulated to be similar to twice daily dosing with the immediate-release formulation. They have the largest immediate-release fraction and shortest duration of the modified-release formulations, lasting between 6 to 8 hours. The dose may be adjusted in 10mg increments at weekly intervals to a maximum of 60mg/day. Although 60mg/day is the maximum licensed dose, the dose may be increased up to 2.1mg/kg daily (max. 90mg/day) under the direction of a specialist.

Methylphenidate must be prescribed by the initiating specialist during initiation and dose stabilisation. The initial maintenance dose must be prescribed by the initiating specialist. Specialist will inform GP on any subsequent doses . GPs should not alter any doses without discussing with specialist unless stopping due to side effects. See section 10.

Where a patient has been switched between medications further monitoring may be required, as per specialist instruction

Duration of treatment

Following an adequate treatment response, medication treatment for ADHD should be continued for as long as it remains clinically effective. This should be reviewed at least annually by the specialist.

Conditions requiring dose adjustment:

Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. This should be undertaken and supervised by the specialist who will advise the patient and primary care prescriber of the outcome.

6.Pharmaceutical aspects

Back to top

Route of administration:	Oral
Formulation:	Methylphenidate hydrochloride. **Standard release tablets:** Medikinet®: 5mg, 10mg, 20mg Methylphenidate hydrochloride (generic): 5mg, 10mg, 20mg Ritalin®: 10mg Tranquilyn®: 5mg, 10mg, 20mg Brand name prescribing is not necessary for standard release tablets. **Prolonged-release tablets (12 hour preparations):** NB: Modified-released preparations vary in their release characteristics and must be prescribed by brand name. The specialist must specify the brand to be prescribed. However, during periods of drug shortages please refer to the APC ADHD shortages page and or Nottinghamshire Joint Formulary for local guidance and support tools. MHRA September 2022 drug safety warning : Caution if switching patients between different long acting formulations of methylphenidate Please refer to the Nottinghamshire Joint Formulary for guidance on preferred brand prescribing. Currently the preferred brands are : Affenid XL ® : 18mg, 27mg, 36mg, 54mg Delmosart®: 18mg, 27mg, 36mg, 54mg Xaggitin XL®: 18mg, 27mg, 36mg, 54mg Other brands include: Atenza XL ® : 18mg, 27mg, 36mg, 54mg Matoride XL®: 18mg, 36mg, 54mg Xenidate XL®: 18mg, 27mg, 36mg, 54mg Concerta XL®: 18mg, 27mg, 36mg, 54mg **Modified-release capsules (8 hour preparations):** NB: Modified-released preparations vary in their release characteristics and must be prescribed by brand name. The specialist must specify the brand to be prescribed. However, during periods of drug shortages please refer to the APC

	ADHD shortages page and or Nottinghamshire Joint Formulary for local guidance and support tools. **MHRA September 2022 drug safety warning: Caution if switching patients between different long acting formulations of methylphenidate** Equasym XL®: 10mg, 20mg, 30mg Focusim XL®**:** 10mg, 20mg, 30mg, 40mg Medikinet XL®: 5mg, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg Meflynate XL®:10mg, 20mg, 30mg, 40mg, 60mg Metyrol XL®:10mg, 20mg, 30mg, 40mg, 60mg Ritalin XL®: 10mg, 20mg, 30mg, 40mg, 60mg
Administration details:	Methylphenidate can be taken with or without food, but patients should standardise which method is chosen. Administration requirements vary by formulation and brand. Methylphenidate capsules can be opened and sprinkled on a small amount of soft food for administration. Please consult the relevant SPC for brand-specific information. If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose.
Other important information:	Methylphenidate is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. The choice of formulation will be decided by the treating specialist on an individual basis, and depends on the intended duration of effect. Risk of misuse can be reduced by using modified-release preparations. Alcohol may exacerbate CNS adverse effects of methylphenidate and should be avoided during use. Methylphenidate may cause false positive laboratory test results for amphetamines.

7.Significant medicine interactions

Back to top

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

Methylphenidate is not metabolised by cytochrome P450 to a clinically relevant extent. Inducers or inhibitors of cytochrome P450 are not expected to have any relevant impact on methylphenidate pharmacokinetics. Conversely, methylphenidate does not relevantly inhibit cytochrome P450 1A2, 2C8, 2C9, 2C19, 2D6, 2E1 or 3A.

- **Monoamine oxidase inhibitors (MAOIs):** risk of hypertensive crisis. The combination should be avoided, and use of methylphenidate and MAOIs should be separated by at least 14 days
- **Coumarin anticoagulants, anticonvulsants (e.g. phenobarbital, phenytoin, primidone), selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants**: metabolism may be inhibited by methylphenidate. Dose adjustment may be required when starting or stopping methylphenidate. Methylphenidate may inhibit the metabolism of coumarin anticoagulants such as warfarin (i.e. enhance the anticoagulant effect). Increased frequency of INR monitoring may be required.
- **Anti-hypertensive drugs**: effectiveness may be reduced by methylphenidate
- **Other drugs which elevate blood pressure:** risk of additive effects (e.g. linezolid). Avoid concomitant use due to risk of hypertensive crisis.
- **Alcohol:** may exacerbate adverse CNS effects of methylphenidate
- **Serotonergic drugs**, including SSRIs and MAOIs**:** increased risk of central nervous system (CNS) adverse effects, risk of serotonin syndrome
- **Halogenated anaesthetics:** risk of sudden blood pressure increase during surgery. Avoid methylphenidate on the day of planned surgery.
- **Dopaminergic drugs**, **including antipsychotics**: increased risk of pharmacodynamic interactions including dyskinesias or hypertensive crisis (e.g. risperidone, paliperidone, selegiline, rasagiline)-avoid
- **Apraclonidine:** effects decreased by methylphenidate.
- **Carbamazepine:** may decrease methylphenidate levels
- **Ozanimod:** may increase risk of hypertensive crisis
- **Clonidine :**A small number of serious adverse events have been reported in patients receiving a combination of clonidine and methylphenidate although causality is not established.
- **H_2 receptor blockers, proton pump inhibitors or antacids** :Medikinet XL must not be taken together with H_2 receptor blockers, proton pump inhibitors or antacids, as this could lead to a faster release of the total amount of active substance.

8. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist

Back to top

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- A full assessment, as recommended by NICE guidance for ADHD. This should include medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required.
- Pre-treatment assessment to be performed will include diagnostic interview, behavioral rating scales (e.g. SDQ, Conners', CAARS self and observer report), descriptive reports from parents and teachers.
- Risk assessment for substance misuse and drug diversion.
- Height, weight (measured and recorded against normal range for age, height and sex), appetite and body mass index (BMI)
- Baseline blood pressure (BP) and heart rate (measured with appropriately sized cuff and compared with normal range for age)
- A cardiovascular assessment.
  An electrocardiogram (ECG) is not needed before starting, methylphenidate unless the person has any features below or a co- existing condition being treated with a medicine that may pose an increased cardiac risk.
- Arrange for electrocardiogram (ECG) /echocardiogram/ refer for cardiology opinion before starting medication, only if the patient has any of the following:
  - History of congenital heart disease or previous cardiac surgery
  - History of sudden death in a first-degree relative under 40 years suggesting a cardiac disease
  - Shortness of breath on exertion compared with peers
  - Fainting on exertion or in response to fright or noise
  - Palpitations that are rapid, regular and start and stop suddenly (fleeting occasional bumps are usually ectopic and do not need investigation)
  - Chest pain suggestive of cardiac origin
  - Signs of heart failure orheart murmur
  - Current treatment with a medicine that may increase cardiac risk
  - Blood pressure that is classified as hypertensive.

Refer to a paediatric hypertension specialist before starting a medication for ADHD if blood pressure is consistently above the 95th centile for age and height for children and young people.

Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website.

Initial monitoring:

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring as no standard is given in literature.
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring (ADHD):

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone or electronic records such as System1 where available

If the child / young person fails to attend for physical monitoring, despite attempts to re-appoint, do not issue any further prescriptions, contact the patient/carer and inform the specialist. The patient should be informed of this policy when treatment begins.

9. Ongoing monitoring requirements to be undertaken by primary care

Back to top

See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
• Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms	Every 6 months, before and after any change of dose recommended by specialist team**. Compare with previous measurements and with the normal range for age. Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website. See section 10 for further guidance on management
• Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder) • Explore whether patient is experiencing any difficulties with sleep	Every 6 months, before and after any change of dose recommended by specialist team.**
• Weight and appetite	Following initiation: • Every 3 months in children 10 years and under. • Measure weight at 3 and 6 months after starting treatment in children over 10 years and young people and every 6 months thereafter, or more often if concern arise. Plot on a growth chart (link: http://www.rcpch.ac.uk/growthcharts). If weight loss or reduced weight gain this should be discussed with the specialist.

• Height	Six monthly. Plot on a growth chart. (link: http://www.rcpch.ac.uk/growthcharts). If growth is affected significantly this should be discussed with the specialist.
• Medication related side effects*	At each visit
• ECG, LFTs, FBC	Not recommended unless there is a clinical indication
• Assessment of adherence, and for any indication of methylphenidate abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
• Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually

*Consider using standard symptom and side effect rating scales during treatment as an adjunct to clinical assessment.

** The specialist should determine the appropriate timing for this monitoring as no standard is given in literature

If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

Back to top

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

European guidelines on managing adverse effects of medication for ADHD were published in 2011. These provide additional guidance for clinicians

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE SPECIALIST TEAM.

If the child in front of you is acutely unwell, please contact the oncall general paediatric team

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
Cardiovascular Sustained resting tachycardia, arrhythmia/palpitations, clinically significant increase in systolic blood pressure is persistently above 95 th centile for age and height.	Withhold or reduce dose and review for acute additional symptoms. If present refer to general paediatric team. If no additional symptoms inform specialist and refer to a paediatric hypertension specialist as soon as possible Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website.
Weight or BMI outside healthy range, anorexia or weight loss	Exclude other reasons for weight loss. Give advice as per NICE NG87: • take medication with or after food, not before

	• additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • obtaining dietary advice • consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Haematological disorders Including leukopenia, thrombocytopenia, anaemia related symptoms (e.g. paleness, lethargy) or other alterations Abnormal bruising / bleeding / severe sore throat / skin lesions or severe infection NB: no haematological monitoring is recommended. Haematological disorders would be a chance finding/due to patient reporting adverse drug reactions.	Seek immediate medical attention, rarely related to methylphenidate.
Psychiatric disorders New or worsening psychiatric symptoms, e.g. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, depression	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present Methylphenidate should not be continued unless the benefits outweigh the risks.
Nervous system disorders Symptoms of cerebral ischaemia, e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory	Discontinue methylphenidate, refer urgently for neurological assessment
New or worsening seizures	Discontinue methylphenidate and discuss with specialist team or oncall team immediately.

Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue methylphenidate and discuss with specialist team or oncall team immediately.
Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics	Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required
Insomnia or other sleep disturbance/nightmares, sedation, sexual dysfunction	Review timing of methylphenidate dose and advise as appropriate. Give advice on sleep hygiene. Discuss with specialist if difficulty persists; dose reduction may be required.
Suspicion of abuse, misuse, or diversion	Discuss with specialist team
Failure to attend for physical monitoring checks	Do not issue further prescriptions, discuss as soon as possible with specialist.

11. Advice to patients and carers

Back to top

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Abnormally sustained or frequent and painful erections: seek immediate medical attention.
- Signs or symptoms of serotonin syndrome (e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea)
- Any mood changes, for example. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, anxiety, depression
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory)
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.

The patient should be advised:

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Not to drive or operate machines if methylphenidate affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or visual disturbances.
- People who drive must inform the DVLA if their ADHD, narcolepsy or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving or https://www.gov.uk/narcolepsy-and-driving.
- Avoid alcohol while taking methylphenidate, as it may make side effects worse. Avoid recreational drugs.
- Not to stop taking methylphenidate without talking to their doctor. Medical supervision of withdrawal is required, since this may unmask depression or chronic over-activity.
- Methylphenidate is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store methylphenidate safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see https://www.gov.uk/guidance/controlled-drugs-personal-licences.

Patient information:

- Royal College of Psychiatrists – https://www.rcpsych.ac.uk/mental-health/parents-and-young-people/information-for-parents-and-carers/ADHD-and-hyperkinetic-disorder-information-for-parents
- NHS – Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/
- https://www.youngminds.org.uk/
- https://youthmed.info/medicines/
- A patient information leaflet is available from: https://www.nhs.uk/medicines/methylphenidate-children/

12. Pregnancy, paternal exposure and breast feeding

Back to top

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Methylphenidate is not recommended for use during pregnancy unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy.

Evidence on exposure to methylphenidate during pregnancy is too limited to draw firm conclusions on adverse outcomes, however caution is advised. Clinicians should be aware that patients may have other risk factors which independently alter the risks.

Patients who become pregnant while taking methylphenidate, or who plan a pregnancy, should be referred to the specialist team for review.

Healthcare professional information available from:

USE OF METHYLPHENIDATE IN PREGNANCY – UKTIS

Patient information available from: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Methylphenidate/

Breastfeeding:

Methylphenidate has been found in breast milk in small amounts. Evidence for safety in breastfeeding is limited. Decisions to use while breastfeeding should be made on a case-by-case basis, taking into account the risks to the infant and benefits of therapy. Infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite/weight gain, sleep disturbances, irritability), although these may be difficult to detect. High doses may interfere with lactation, although this is not confirmed in practice.

Healthcare professional information available from: https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/

Paternal exposure:
No evidence regarding adverse outcomes following paternal exposure was identified.
Further information for patients: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org)

13. Specialist contact information

Back to top

IN HOURS

Child and Adolescent Mental Health Services (CAMHS) Mansfield-Ashfield 01623-65092

Newark-Sherwood 01636-670633

Child and Adolescent Mental Health Services (CAMHS 0115 8440500

Community Paediatrics (Queens Medical Centre NUH) 0115 840 4848.

Community Paediatrics - Mansfield, Newark, Ollerton, Ashfield (excluding Hucknall) at Sherwood Forest Hospitals NHS Foundation Trust

01623-622515

Nottinghamshire Healthcare NHS Foundation Trust Pharmacy advice line (for healthcare professionals): 0300 303 5808 and email: MI@nottshc.nhs.uk

Nottingham University Hospital QMC Pharmacy Medicines Information 0115 924 9924 Extension 84185/81200

Sherwood Forest Hospitals NHS Foundation Trust Pharmacy Medicine Information 01623-672213
Wells Road Centre Pharmacy Medicine information01159-555357

Out of Hours
Contact on-call CAMHS Psychiatrist via Nottinghamshire Healthcare NHS Foundation Trust 0118440500

Oncall Paediatricians

Sherwood Forest Hospitals On Call Paediatrician 01623 622 515

Nottinghamshire South (Nottingham University Hospital QMC) 0115-8831181
Nottinghamshire North (Sherwood Forest Hospitals NHS Foundation Trust) 01623-622515.

Other local NHS specialists may request shared care including local mental health teams and intellectual disability teams. The contact details for these teams will be detailed on the shared care request letter.

14. Additional information

Back to top

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

Back to top

- eBNFC. Methylphenidate. Accessed via https://bnfc.nice.org.uk/ on 07/02/2023
- Methylphenidate hydrochloride 5 mg tablets (Medikinet®). Date of revision of the text October 2022. Accessed via https://www.medicines.org.uk/emc/product/328/smpc
- Methylphenidate hydrochloride 10 mg tablets (Ritalin®). Date of revision of the text 10/12/20. Accessed via https://www.medicines.org.uk/emc/product/1035/smpc
- Methylphenidate hydrochloride 5 mg tablets (Tranquilyn®). Date of revision of the text 21/09/20. Accessed via https://products.mhra.gov.uk/
- Methylphenidate hydrochloride 5 mg tablets (Mylan). Date of revision of the text October 2022. Accessed via https://www.medicines.org.uk/emc/product/8724/smpc
- Methylphenidate hydrochloride 18 mg prolonged-release tablets (Concerta XL®). Date of revision of the text 02/11/22. Accessed via https://www.medicines.org.uk/emc/product/6872/smpc
- Methylphenidate hydrochloride 18 mg prolonged-release tablets (Delmosart®). Date of revision of the text 21/09/20. Accessed via Dosage may be altered by specialists to reflect the child's current physical condition, symptoms or social demands. The patient should require no extra monitoring than already described in this guidance if dosage is adjusted by the specialist in this wayhttps://www.medicines.org.uk/emc/product/2337/smpc – SPC currently unavailable
- Methylphenidate hydrochloride 18 mg prolonged-release tablets (Matoride XL®). Date of revision of the text 02/09/2022. Accessed via https://www.medicines.org.uk/emc/product/3682/smpc
- Methylphenidate hydrochloride 18 mg prolonged-release tablets (Xaggitin XL®). Date of revision of the text September 2022. Accessed via https://www.medicines.org.uk/emc/product/2704/smpc

- Methylphenidate hydrochloride 18 mg prolonged-release tablets (Xenidate XL®). Date of revision of the text October 2022. Accessed via https://www.medicines.org.uk/emc/product/4397/smpc
- Methylphenidate hydrochloride 10 mg prolonged-release capsules (Equasym XL®). Date of revision of the text 21/09/2022. Accessed via https://www.medicines.org.uk/emc/product/3887/smpc
- Methylphenidate hydrochloride 10 mg prolonged-release capsules (Medikinet XL®▼). Date of revision of the text 29/01/2021. Accessed via https://www.medicines.org.uk/emc/product/313/smpc
- Methylphenidate hydrochloride 10 mg prolonged-release capsules (Ritalin XL®). Date of revision of the text 03/11/20. Accessed via https://www.medicines.org.uk/emc/product/11094/smpc- SPC currently unavailable
- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 07/02/2022
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Methylphenidate. Last revised January 2021. Accessed via https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/methylphenidate/ on 07/02/2022
- Specialist Pharmacy Service. Medicines Q&A: Which medicines should be considered for brand-name prescribing in primary care? Prescribing by generic or brand name in primary care – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice last updated 13/09/2022. Accessed on 07/02/2023
- Home Office. Guidance: List of most commonly encountered drugs currently controlled under the misuse of drugs legislation. Updated August 2022. Accessed via https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation on 05/05/2021
- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via https://www.nice.org.uk/guidance/ng46/ on 05/05/2021
- Methylphenidate (MPH): physician's guide to prescribing. Accessed via http://www.methylphenidate-guide.eu/gb/welcome.php on 07/02/23
- Evidence-based guidelines for the pharmacological management of attention deficit hyperactivity disorder: Update on recommendations from the British Association for Psychopharmacology. Bolea-Alamañac B, Nutt DJ, Adamou M, et al. Journal of Psychopharmacology. 2014. 1–25. DOI: 10.1177/0269881113519509
- UKTIS. Use of methylphenidate in pregnancy. Last updated January 2018. Accessed via https://www.toxbase.org/poisons-index-a-z/m-products/methylphenidate-in-pregnancy/ on 14/04/2021

- Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/ on 07/02/2023
- Specialist Pharmacy Service. Methylphenidate Lactation Safety Information. Last updated June 2021. Accessed via https://www.sps.nhs.uk/medicines/methylphenidate/ on 07/02/2023
- Graham J et al. European guidelines on managing adverse effects of medication for ADHD. Eur Child Adolesc Psychiatry (2011), 20:17-37. On-line at European guidelines on managing adverse effects of medication for ADHD - PMC (nih.gov)
- Nottinghamshire Area Prescribing Committee. September 2020. Blood pressure and heart rate monitoring in children. Information Sheet for Primary Care Prescribers. Available from https://www.nottsapc.nhs.uk/media/1627/bp_and_hr_monitoring_for_children.pdf. Last accessed on 07/02/2023
- MHRA- Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations. Last updated September 202 Available from Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations - GOV.UK (www.gov.uk). Accessed on 07/02/2023
-

16. Other relevant national guidance

Back to top

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

Back to top

Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

- Prescribing and monitoring responsibility will only be transferred when the patient's condition and medication are stable.
- The specialist will request shared care with the GP in writing.

- If the GP doesn’t agree to shared care, they should inform the specialist of their decision in writing within 14 days.
- In cases where shared care arrangements are not in place or where problems have arisen within the agreement and patient care may be affected, the responsibility for the patients’ management including prescribing reverts to the specialist.
- Should the patient’s condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter