## Methylphenidate for patients within children and adult services

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| Version: | RDTC v1.0 | Replaces version: | NHSE v1.0 |
| Clinical content last reviewed: | May 2024 | Next review date: | May 2026 |

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| **Version** | **Date published** | **Changes since previous version** |
| RDTC v1.0 | 12/06/24 | Hyperlinks and references updated to current versions, list of methylphenidate products updated to reflect current availability and licensing differences, additional drug interactions added, inclusion of MHRA & SPS advice regarding switching MR formulations, pregnancy section updated with current information from UKTIS, minor content clarifications and alignment of content with other ADHD SCPs. |
| HNY | 28/04/24 | The RDTC version has been adjusted to include children as well as adults within the same document.  Section 1: Include reference to children as well.  Section 2: Added in children for the ADHD indication.  Section 3: For the treatment of ADHD from the age of 6 years  Section 4: State that prescribing and monitoring should be transferred after at least 12 weeks.  Section 4: Initial stabilisation section expanded;   * Immediate release tablets   Children (6-17 years): 5 mg 1-2 times daily, increased if necessary at weekly intervals by 5-10 mg daily  Adults: 5 mg twice daily, increased if necessary at weekly intervals by 5-10 mg daily   * Modified release tablets   Children & Adults – 18 mg once daily, increased if necessary at weekly intervals by 18 mg daily   * Modified release capsules   Children & Adults – 10 mg once daily, increased if necessary at weekly intervals by 10 mg daily  Maintenance dose section:  Maximum dose in ADHD:   * Immediate release tablets:   Adults: up to 100mg daily in 2-3 divided doses  Children: up to 90mg daily in 2-3 divided doses   * Modified release tablets:   Children and adults: up to 108mg once daily, taken in the morning   * Modified release capsules:   Adults: up to 100mg daily. May be taken as a single dose in the morning or in divided doses in the morning and at midday, depending on brand.  Children: up to 90mg daily.  Section 5: Baseline investigations   * Blood pressure (BP) and heart rate - recorded on centile chart (not applicable in patients > 18 years) * Height, weight and body mass index (BMI) - recorded on centile chart (not applicable in patients > 18 years)   Initial monitoring:  Prior to there being a shared care agreement in place:   * Height:   Children aged 6 to 17 years of age – 6-monthly   * Weight:   Children aged 6 to 10 years of age – 3-monthly  Children aged 11 to 17 years of age – at 3 months, 6 months, then 6-monthly thereafter  Adults: 6-monthly   * After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms, including aggressive or hostile behaviour and tics. The specialist should determine the appropriate timing for this monitoring. For under 18s, record BP, height and weight on centile charts to detect clinically important changes.   Ongoing monitoring section  If still on treatment at school-leaving age, determine if treatment needs to be continued and, if it does, arrange for transition to adult services by 18 years of age.  Section 6  For under 18s, record BP, height and weight on centile charts to detect clinically important changes.  Other important information  Limit prescriptions to a 28-to-30-day supply in line with good practice relating to CDs.  Section 13:  Details for contacting specialist must be included on clinic letter.  Section 14:  Notify specialist immediately (within 2 weeks) if transfer of prescribing and monitoring responsibility is not accepted so that alternative arrangements can be put in place  Contact specialist if communication of prescribing & monitoring requirements is unclear. |

**Local review and adoption**

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| **Local approval** | **Date** |
| Local content added |  |
| Approved for use by HNY ICB |  |
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Clinical content has been reviewed and updated by the RDTC on the date indicated above. Every effort is made to keep the content up to date. These templates are provided to the North West and North East and Yorkshire ICBs for localisation and approval through standard ICB processes. The most recent version is available on the RDTC website at <https://rdtc.nhs.uk/prescribing-support-document/shared-care-protocol-methylphenidate-in-adults/>.

Information requiring local completion is highlighted.

This document is intended for use by NHS healthcare professionals and cannot be used for commercial or marketing purposes.

**Shared Care Protocol**

## Methylphenidate for patients within children and adult services

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| Background | Methylphenidate is a central nervous system stimulant licensed as part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD). It may be offered as a first line pharmacological treatment option for children and adults with ADHD who have been appropriately diagnosed (see NICE Guidance [NG87](https://www.nice.org.uk/guidance/ng87) ADHD: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural, and occupational or educational needs.  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 vary in their release characteristics and clinical effect. Modified-released preparations should therefore be prescribed by brand name, or by using generic drug name and name of the manufacturer. Caution should be exercised if switching between these products as advised by the [MHRA](https://www.gov.uk/drug-safety-update/methylphenidate-long-acting-modified-release-preparations-caution-if-switching-between-products-due-to-differences-in-formulations).  Methylphenidate is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance [NG46](https://www.nice.org.uk/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) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated. NICE Guidance [NG43](https://www.nice.org.uk/guidance/ng43) Transition from children’s to adults’ services for young people using health or social care services should be followed.  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.  Methylphenidate is not licensed for all the indications it is used to treat below. However, its use for the indications below are established and supported by various sources and bodies including the BNF and NICE. |
| Licensed and agreed off-label indications | * Attention deficit hyperactivity disorder (ADHD) in children and adults * Narcolepsyǂ   ǂ Off-label indication. Please note licensed indications vary by manufacturer; see [SPCs](https://www.medicines.org.uk/emc/search?q=methylphenidate) for full details. Some brands are not licensed in adults (see [section 7](#_Pharmaceutical_aspects))  This shared care protocol applies to children and adults. |
| Locally agreed indications | For the treatment of ADHD from the age of 6 years |
| Initiation and ongoing dose regime | Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks and when the patient’s dose has been optimised and with satisfactory investigation results for at least 12 weeks.  The duration of treatment and 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 specialist unless directions have been discussed and agreed with the primary care clinician.  Termination of treatment will be the responsibility of the specialist.  **Initial stabilisation:**  **Recommended starting dose in ADHD**:   * Immediate release tablets   Children (6-17 years): 5 mg 1-2 times daily, increased if necessary at weekly intervals by 5-10 mg daily  Adults: 5 mg twice daily, increased if necessary at weekly intervals by 5-10 mg daily   * Modified release tablets   Children & Adults – 18 mg once daily, increased if necessary at weekly intervals by 18 mg daily   * Modified release capsules   Children & Adults – 10 mg once daily, increased if necessary at weekly intervals by 10 mg daily  Adults with ADHD who have shown clear benefit from methylphenidate in childhood or adolescence may continue treatment into adulthood at the same daily dose. Consult [SPC](https://www.medicines.org.uk/emc/search?q=methylphenidate) for the prescribed brand for more information.  **Recommended starting dose in narcolepsy (off-label)**:   * Immediate release tablets: 10mg daily in divided doses, to be taken before meals   **The loading period must be prescribed by the initiating specialist.**  **Maintenance dose (following initial stabilisation):**  **The dose of methylphenidate should be titrated to response, usually at weekly intervals.**  **Maximum dose in ADHD:**   * Immediate release tablets:   Adults: up to 100mg daily in 2-3 divided doses  Children: up to 90mg daily in 2-3 divided doses   * Modified release tablets:   Children and adults: up to 108mg once daily, taken in the morning   * Modified release capsules:   Adults: up to 100mg daily. May be taken as a single dose in the morning or in divided doses in the morning and at midday, depending on brand.  Children: up to 90mg daily.  The maximum licensed daily dose varies with formulation and brand. The maximum doses quoted above are off label but align with BNF recommendations. Consult [BNF](https://bnf.nice.org.uk/drug/methylphenidate-hydrochloride.html) and [SPCs](https://www.medicines.org.uk/emc/search?q=methylphenidate) for further details.  **Usual dose in narcolepsy (off-label):**   * Immediate release tablets: 20-30mg daily in divided doses, taken before meals. Maximum dose 60mg daily.   **The initial maintenance dose must be prescribed by the initiating 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. |
| Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist | 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 the immediate future will prescribing and monitoring be transferred to primary care.  **Baseline investigations:**   * A full assessment, as recommended by [NICE guidance for ADHD](https://www.nice.org.uk/guidance/ng87/chapter/Recommendations#medication). This should ensure that the patient meets the criteria for ADHD and that pharmacological treatment is required. The assessment should also include a medical history and cardiovascular assessment, considering conditions that may be contraindications for methylphenidate, and risk of pregnancy (where applicable). * A risk assessment for substance misuse and drug diversion * Blood pressure (BP) and heart rate - recorded on centile chart (not applicable in patients > 18 years) * Height, weight and body mass index (BMI) - recorded on centile chart (not applicable in patients > 18 years) * Appetite * Electrocardiogram (ECG) and cardiology opinion are recommended if the patient has any of the following:   + history of congenital heart disease or previous cardiac surgery   + 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   + chest pain suggestive of cardiac origin   + signs of heart failure, heart murmur or hypertension * ECG is recommended if the patient has a co-existing condition treated with a medicine that may increase cardiac risk.   **Initial monitoring:**   * Before every change of dose: assess heart rate, blood pressure, appetite and weight.   Prior to there being a shared care agreement in place:   * Height:   Children aged 6 to 17 years of age – 6-monthly   * Weight:   Children aged 6 to 10 years of age – 3-monthly  Children aged 11 to 17 years of age – at 3 months, 6 months, then 6-monthly thereafter  Adults: 6-monthly   * After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms, including aggressive or hostile behaviour and tics. The specialist should determine the appropriate timing for this monitoring. For under 18s, record BP, height and weight on centile charts to detect clinically important changes. * Assessment of symptom improvement. Discontinue if no improvement is observed after one month.   **Ongoing monitoring:**   * Monitoring before and after dose adjustments, as above.   Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and 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 (preferably during school holidays if in education). If continuing medication, document the reasons why. If still on treatment at school-leaving age, determine if treatment needs to be continued and, if it does, arrange for transition to adult services by 18 years of age.  Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 6](#_Ongoing_monitoring_requirements) remains appropriate. |

## Ongoing monitoring requirements to be undertaken by primary care unless completed at review by specialist team

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.

| **Monitoring** | **Frequency** |
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| * Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms * Weight and appetite and height (for under 18s) * Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, depression, symptoms of bipolar disorder, aggressive or hostile behaviour) * Explore whether patient is experiencing any difficulties with sleep | Every 6 months, and after any change of dose recommended by, and agreed with the specialist team.  For under 18s, record BP, height and weight on centile charts to detect clinically important changes. |
| Assessment of adherence, and for any indication of methylphenidate abuse, misuse, or diversion | As required, based on the patient’s needs and individual circumstances |
| ADHD patients: Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD | Annually |

## Pharmaceutical aspects

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| 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  **NB: Methylphenidate standard release tablets are not licensed for use in adults. Use in adults is considered off-label.** Brand name prescribing is not necessary for standard release tablets.  **Prolonged-release tablets:**  Modified-released preparations vary in their release characteristics and must be prescribed by brand name, or by using the generic drug name and name of the manufacturer. The specialist must specify the brand to be prescribed.  Affenid XL®: 18mg, 27mg, 36mg, 54mg  Concerta XL®: 18mg, 27mg, 36mg, 54mg  Delmosart®: 18mg, 27mg, 36mg, 54mg  Matoride XL®: 18mg, 36mg, 54mg  Xaggitin XL®: 18mg, 27mg, 36mg, 54mg  Xenidate XL®: 18mg, 27mg, 36mg, 54mg  **NB: Some methylphenidate prolonged-release tablets are licensed for continuation in adults who have shown clear benefit from treatment in childhood and/or adolescence and are not licensed for initiation in adults. Their use in this way is considered off-label.**  **Modified-release capsules:**  Modified-released preparations vary in their release characteristics and must be prescribed by brand name or by using the generic drug name and name of the manufacturer. The specialist must specify the brand to be prescribed.  Equasym XL®: 10mg, 20mg, 30mg  Medikinet XL®: 5mg, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg  Meflynate XL®: 10mg, 20mg, 30mg, 40mg, 60mg  Metyrol XL®: 10mg, 20mg, 30mg, 40mg, 60mg  **NB: Equasym XL is not licensed for use in adults. Use in adults is considered off-label.**  **Oral solution:**  Methylphenidate hydrochloride 2mg/ml oral solution  **NB: Methylphenidate oral solution is not licensed for use in adults. Use in adults is considered off-label.**  **Please consult the relevant** [**SPC**](https://www.medicines.org.uk/emc/search?q=methylphenidate) **for brand-specific licensing information.** |
| Administration details: | Administration requirements vary by formulation and brand. Methylphenidate modified release capsules can be opened and sprinkled on a small amount of soft food for administration. Methylphenidate modified release tablets should be swallowed whole with sufficient fluid and not chewed, divided or crushed. Please consult the relevant [SPC](https://www.medicines.org.uk/emc/search?q=methylphenidate) 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: | Caution is required if switching patients between different modified-release formulations of methylphenidate as different instructions for use and different release profiles may affect symptom management. For further advice, refer to [MHRA](https://www.gov.uk/drug-safety-update/methylphenidate-long-acting-modified-release-preparations-caution-if-switching-between-products-due-to-differences-in-formulations) and the [Specialist Pharmacy Service](https://www.sps.nhs.uk/articles/considerations-when-prescribing-modified-release-methylphenidate/).  Methylphenidate is a schedule 2 controlled drug and is subject to [legal prescription requirements](https://bnf.nice.org.uk/guidance/controlled-drugs-and-drug-dependence.html). It has the potential for misuse and diversion. Limit prescriptions to a 28-to-30-day supply in line with good practice relating to CDs.  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 amfetamines. |

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| Cautions and contraindications | This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see [BNF](https://bnf.nice.org.uk/) & [SPC](https://www.medicines.org.uk/emc/search?q=methylphenidate) for comprehensive information.  **Contraindications:**   * Hypersensitivity to methylphenidate or to any of the excipients * Glaucoma * Phaeochromocytoma * During treatment with non-selective, irreversible monoamine oxidase inhibitors (MAOI), or within a minimum of 14 days of discontinuing these drugs, due to the risk of hypertensive crisis * Hyperthyroidism or thyrotoxicosis * Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, 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 6](#_Ongoing_monitoring_requirements) & [section 10](#_Adverse_effects_and)) * 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: patients should be screened for risk of bipolar disorder, including detailed psychiatric and family history of suicide, bipolar disorder and depression. * 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 have not been established in patients older than 60-65 years of age. * Susceptibility to angle-closure glaucoma. * Pregnancy or breast-feeding (see [section 12](#_Pregnancy,_paternal_exposure)) * Potential for abuse, misuse, or diversion. * Avoid abrupt withdrawal |
| Significant drug interactions | The following list is not exhaustive. Please see [BNF](https://bnf.nice.org.uk/) & [SPC](https://www.medicines.org.uk/emc/search?q=methylphenidate) for comprehensive information and recommended management.   * **MAOIs (e.g. rasagiline, selegiline, isocarboxazid, tranylcypromine):** risk of hypertensive crisis. Concomitant use is contraindicated (see [section 8](#_Cautions_and_contraindications)). * **Centrally acting alpha-2 agonists (e.g. clonidine)**: serious adverse events including sudden death have been reported with concomitant use. Long-term safety of combined use has not been systemically evaluated. * **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. * **Anti-hypertensive drugs**: effectiveness may be reduced by methylphenidate * **Other drugs which elevate blood pressure (e.g. linezolid):** risk of additive effects * **Alcohol:** may exacerbate adverse CNS effects of methylphenidate; avoid. * **Serotonergic drugs, including SSRIs and MAOIs:** increased risk of central nervous system (CNS) adverse effects and serotonin syndrome. * **Halogenated anaesthetics:** risk of sudden blood pressure and heart rate increase during surgery. Avoid methylphenidate on the day of planned surgery. * **Dopaminergic drugs**, **including antipsychotics (e.g. TCAs, risperidone, paliperidone, selegiline, rasagiline)**: increased risk of pharmacodynamic interactions e.g. dyskinesias or hypertensive crisis * **Apraclonidine:** effects decreased by methylphenidate. * **Carbamazepine:** may decrease methylphenidate levels * **Ozanimod:** may increase risk of hypertensive crisis * **Valproate:** may enhance effects of methylphenidate * **Nirmatrelvir boosted with ritonavir:** may increase methylphenidate levels * **Medikinet XL only:** must not be taken together with H2 receptor blockers, proton pump inhibitors or antacids, as this could lead to a faster release of the total amount of active substance (see [section 8](#_Cautions_and_contraindications)). |

## Adverse effects and management

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**.** For information on incidence of ADRs see relevant SPCs.

**Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** <https://yellowcard.mhra.gov.uk/>.

Advice based on shared care guidelines published by NHS England and checked against current guidance.

| **Adverse effect** | **Management** |
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| **Cardiovascular**  Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP (≥15–20 mmHg or systolic BP > 95th centile) | * In context of recent dose increase, revert to previous dose and discuss with specialist team for ongoing management * In absence of recent dose changes, reduce dose by half and discuss with specialist team or cardiology for further advice. |
| **Weight or BMI outside healthy range**, anorexia or weight loss | Exclude other reasons for weight loss. Give advice as per [NICE NG87](https://www.nice.org.uk/guidance/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. |
| **Gastrointestinal disorders**  Abdominal pain, diarrhoea, nausea, stomach discomfort, vomiting | Usually occur at the beginning of treatment and may be alleviated by concomitant food intake. Discuss with specialist team if difficulty persists. |
| **Haematological disorders**  Including leukopenia, thrombocytopenia, anaemia or other alterations  NB: no haematological monitoring is recommended. Haematological disorders would be a chance finding/due to patient reporting adverse drug reactions. | Contact specialist team. Discontinuation should be considered. Referral to haematology may be warranted; use clinical discretion. |
| **Psychiatric disorders**  New or worsening psychiatric or neuropsychiatric 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. |
| Insomnia or other sleep disturbance | 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. |
| **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. Discuss with specialist team. |
| Headache, dizziness | Continue treatment unless severe. Discuss with specialist team if difficulty persists. |
| Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea | Discontinue methylphenidate as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary.  Discuss with specialist team to determine whether methylphenidate can be re-started. |
| Suspicion of abuse, misuse, or diversion | Discuss with specialist team |

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| Advice to patients and carers 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 drugs. | **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) * New or worsening psychiatric symptoms (e.g. anxiety, depressive symptoms, agitation or tension, psychotic or manic symptoms, aggressive or hostile behaviour, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics (including Tourette’s syndrome). * New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory) * Symptoms suggestive of hepatic injury (e.g. new onset severe or persistent abdominal pain, unexplained nausea, malaise, jaundice or darkening of urine). * Skin rashes, or bruising easily * Any visual changes such as difficulty with accommodation or blurring of vision. * 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, cycle, 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 – ADHD in adults. <https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults> * NHS – Attention Deficit Hyperactivity Disorder. <https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/> * Narcolepsy UK - <https://www.narcolepsy.org.uk/resources/methylphenidate> * NHS – Narcolepsy - <https://www.nhs.uk/conditions/narcolepsy/>   **Patient information leaflets (ADHD) are also available from:**  <https://www.medicines.org.uk/emc/search?q=methylphenidate> |
| Pregnancy, paternal exposure and breastfeeding | 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.  The available data on therapeutic methylphenidate use during pregnancy do not suggest a significant increase in overall congenital malformation rates. However, the data are too limited to exclude increased risks, particularly of less common outcomes. Some studies suggest an increased risk of miscarriage with early pregnancy use, and a non-causal association with fetal cardiac malformation. Similar to other CNS-acting drugs, neonatal withdrawal symptoms may be expected following the use of methylphenidate during pregnancy.  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. The specialist will reassume prescribing responsibility, ending the shared care agreement.  Information for healthcare professionals: [UK Teratology Information Service](https://uktis.org/monographs/use-of-methylphenidate-in-pregnancy/)  Information for patients: [Best Use of Medicines in Pregnancy](https://www.medicinesinpregnancy.org/leaflets-a-z/therapeutic-amfetamines/)  **Breastfeeding**:  Methylphenidate when used therapeutically has been found in breast milk in small amounts. Evidence for safety in breastfeeding is limited. The decision 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. High doses may interfere with lactation, although this is not confirmed in practice. If breastfeeding does take place, infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite, slow weight gain, sleep disturbances, irritability), although these may be difficult to detect. For further support, contact the [UK Drugs in Lactation Advisory Service](https://www.sps.nhs.uk/home/about-sps/get-in-touch/medicines-information-services-contact-details/breastfeeding-medicines-advice-service/).  **Paternal exposure**:  No data regarding outcomes following paternal exposure was identified. |
| Specialist contact information and arrangements for referral | Details for contacting specialist must be included on clinic letter. |
| Additional information | 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.  Notify specialist immediately (within 2 weeks) if transfer of prescribing and monitoring responsibility is not accepted so that alternative arrangements can be put in place  Contact specialist if communication of prescribing & monitoring requirements is unclear. |
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| To be read in conjunction with the following documents | * 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/>. |