



# Shared Care Protocol: Methylphenidate for patients within adult services

<b>Title:</b>	Shared Care Protocol: Methylphenidate for patients within adult services – For use in Berkshire East and Berkshire West only
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<b>Change History:</b>	Final 1.0 May 2023

## Shared care protocol:

# Methylphenidate in adult services in Berkshire East and Berkshire West

As well these protocols, 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.

### 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).
- Review baseline investigations and initial monitoring (see section 8 and section 17).
- Initiate and optimise treatment as outlined in section 5. Prescribe the maintenance treatment until optimised.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, send report to 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 contact information (section 13 and 17).
- Prescribe sufficient medication to enable transfer to primary 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.
- Provide specialist advice if the patient becomes or plans to become pregnant and wishes to continue medication. ADHD medication is not recommended to continue unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy (See SmPC).
- Provide advice to primary care on the management of adverse effects if required.

### Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- 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.
- 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.
- Seek specialist advice if the patient becomes or plans to become pregnant and wishes to continue medication. ADHD medication is not recommended to continue unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy (See SmPC).
- Stop treatment as appropriate (See Section 17).

## 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 recreational drugs and be aware that alcohol may make side effects from your treatment worse.
- 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 use effective contraception, 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

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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 adults with ADHD who have been appropriately diagnosed (see NICE Guidance NG87 Attention deficit hyperactivity disorder: 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 therefore vary in their release characteristics and clinical effect. Modified-released preparations should therefore be prescribed by brand name.

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) 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.

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.

## 2. Indications

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- Attention deficit hyperactivity disorder (ADHD) in adults

Please note licensed indications vary by manufacturer; see [SPC](#) for full details. Some brands are not licensed in adults (see [section 6](#))

## 3. Locally agreed off-label use

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Nil.

## 4. Contraindications and cautions

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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
- Glaucoma
- Pheochromocytoma
- 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, 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 acidity 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](#))
- 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

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- Transfer of monitoring and prescribing to primary care is when the patient's dose has been optimised.
- 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.

### Initial stabilisation:

#### Recommended starting dose in ADHD:

- [Immediate release tablets](#): 5 mg, given 2-3 times daily
- [Modified release tablets](#): 18 mg daily, given in the morning
- [Modified release capsules](#): 10-20 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 for the prescribed brand for more information.](#)

During initiation Methylphenidate must be prescribed by the initiating specialist during initiation and dose stabilisation.

**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: up to 100 mg daily in 2-3 divided doses
- Modified release tablets: up to 108 mg once daily, given in the morning
- Modified release capsules: up to 100 mg daily. May be given as a single dose in the morning or in divided doses in the morning and at midday, depending on brand.

The maximum licensed daily dose varies with formulation and brand; consult [BNF](#) and [SPC](#).

**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. Advice can be sought from the specialist where needed.

## 6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	<p>Methylphenidate hydrochloride: <b><u>Standard release tablets:</u></b> Medikinet®: 5mg, 10mg, 20mg Methylphenidate hydrochloride (generic): 5mg, 10mg, 20mg Ritalin®: 10mg Tranquilyn®: 5mg, 10mg, 20mg <b>NB: Methylphenidate standard release tablets are not licensed for use in adults. Use is considered off-label.</b> Brand name prescribing is not necessary for standard release tablets.</p> <p><b><u>Prolonged release preparations</u></b> (see information under 'Prolonged-release tablets' and 'Prolonged-release capsules' for local formulary options):</p> <p>The Medicines and Healthcare products Regulatory Agency (MHRA) has advised that prescribers and dispensers should use caution if switching patients between different long-acting formulations of methylphenidate. This is due to different instructions for use and different release profiles which may affect symptom management. <a href="#">Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations - GOV.UK (www.gov.uk)</a></p> <p>The Specialist Pharmacy Service (SPS) review of the pharmacokinetic profiles of <a href="#">Extended-release-methylphenidate-3.pdf (sps.nhs.uk)</a> provides helpful information about bioequivalence of the available products. The separate release profiles of the three types of prolonged-release preparations, allows prescribers a choice of preparations to match a patient's needs.</p> <p><u>Tables A and B: Release profiles of different brands of M/R methylphenidate*</u></p>

A)

Type	Release of the methylphenidate	Trade names	How it is made
1	Two peaks, second much higher, effect lasts about 18hrs (22-25% quick release, 75-78% slower)	Concerta XL®	OROS® 3-compartment
		Matoride XL®, Xaggitin XL®*, Delmosart XL®*	OROS® 2-compartment
		Tranquilyn® Xenidate XL®	Beaded wax pellets
2	More even throughout day, initial peak lower than second peak (30% quick release, 70% slower)	Equasym XL®	Beaded wax pellets (two sizes)
3	Higher and quicker first peak, lower second peak (50% quick release, 50% slower)	Medikinet XL®	Beaded wax pellets (two sizes)

NB Xaggitin® and Delmosart® are the same tablets but with different names and in different packages.  
 OROS (Osmotic-controlled Release Oral delivery System) has an outer quick release coat and an inner piston slower release.

B)

Product	Strengths, size and what they look like	Release		How much there is in your blood after you take a dose	Practical advice
		0-4hrs	Later		
<b>Methylphenidate</b>					
<b>Concerta XL®</b> (3 chamber OROS capsule-shaped tablet)	18mg		22%	78%	<ul style="list-style-type: none"> <li>Take before, with or after breakfast</li> <li>Swallow whole - do not chew.</li> </ul>
	27mg				
	36mg				
	54mg				
<b>Xenidate XL®</b> (wax pellet tablets)	18mg		22%	78%	<ul style="list-style-type: none"> <li>Take <b>with or after</b> food</li> <li>Swallow whole</li> <li>Can be halved.</li> </ul>
	27mg				
	36mg				
	54mg				
<b>Matoride XL®</b> (2 chamber OROS tablet)	18mg		22%	78%	<ul style="list-style-type: none"> <li>Take <b>before, with or after breakfast</b></li> <li>Swallow whole - do not chew.</li> </ul>
	36mg				
	54mg				
<b>Delmosart®</b>	18mg		25%	75%	<ul style="list-style-type: none"> <li>Take <b>before, with or after breakfast</b></li> <li>Swallow whole - do not chew, break, divide or crush.</li> </ul>
	27mg				
	36mg				
	54mg				
<b>Xaggitin®</b>	18mg		25%	75%	<ul style="list-style-type: none"> <li>Take <b>before, with or after breakfast</b></li> <li>Swallow whole - do not chew, break, divide or crush.</li> </ul>
	27mg				
	36mg				
	54mg				
<b>Equasym XL®</b> (wax pellets in a capsule)	10mg		30%	70%	<ul style="list-style-type: none"> <li>Take <b>before</b> breakfast</li> <li>Swallow whole, or sprinkle contents onto apple sauce and swallow straight away</li> </ul>
	20mg				
	30mg				
<b>Medikinet XL®</b> (wax pellets in a capsule)	5mg		50%	50%	<ul style="list-style-type: none"> <li>Take <b>with or after</b> breakfast</li> <li>Swallow whole, or open and sprinkle onto apple sauce and swallow straight away</li> <li>Do not chew or crush.</li> </ul>
	10mg				
	20mg				
	30mg				
	40mg				
	50mg				
60mg					
<p><i>The different brands of methylphenidate may not be exactly the same.            If you switch products, sometimes your symptoms may not be as well managed.            Talk to your prescriber if this happens if you switch from one product to another.</i></p>					

\*Tables above have been copied from Choice and Medication (C&M) 'Handy Fact Sheet' with kind permission from author (November 2022). Please note use of this information by services not subscribing to the C&M portal resources is not covered by C&M indemnity arrangements.

**Prolonged-release tablets:**

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.  
 Concerta XL®: 18mg, 27mg, 36mg, 54mg



	<p>Delmosart®: 18mg, 27mg, 36mg, 54mg  Matoride XL®: 18mg, 36mg, 54mg  Xaggitin XL®: 18mg, 27mg, 36mg, 54mg  Xenidate XL®: 18mg, 27mg, 36mg, 54mg</p> <p>As the ‘branded generics’ Delmosart XL, Matoride XL, Xaggitin XL and Xenidate XL have been granted replicate marketing authorisation to Concerta XL on the basis that they have satisfied the criteria for equivalent release profile for the reference Concerta XL product, and are approximately half the cost, <b>local formularies restrict the use of Concerta XL</b> to exceptional cases, where branded generics have been deemed to be unsuitable e.g. patients who have switched from a stable dose of Concerta XL and experienced a clear change in symptom control or where there are supply issues with the branded generics.</p> <p><b>For Berkshire Healthcare’s formulary choices for prolonged-release methylphenidate tablet, see <a href="http://westberksformulary.nhs.uk">Berkshire West NHS Formulary (westberksformulary.nhs.uk)</a></b></p> <p>NB: Methylphenidate prolonged-release tablets are licensed for continuation in adults who have shown clear benefit from treatment in childhood and/or adolescence. They are not licensed for initiation in adults. Use in this way is considered off-label.</p> <p><b>Modified-release capsules:</b>  NB: Modified-released preparations vary in their release characteristics and <u>must be prescribed by brand name</u>. The specialist must specify the brand to be prescribed.  Equasym XL®: 10mg, 20mg, 30mg  Medikinet XL®▼: 5mg, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg  Ritalin XL®: 10mg, 20mg, 30mg, 40mg, 60mg</p> <p><b>For Berkshire Healthcare’s formulary choices for prolonged-release methylphenidate capsules, see <a href="http://westberksformulary.nhs.uk">Berkshire West NHS Formulary (westberksformulary.nhs.uk)</a></b></p> <p>NB: Ritalin XL and Medikinet XL modified-release capsules are licensed for initiation and continuation in adults. Equasym XL is not licensed for use in adults. Please consult the relevant <a href="#">SPC</a> for brand-specific licensing information.</p>
Administration details:	<p>Methylphenidate can be taken with or without food, but patients should standardise which method is chosen.</p> <p>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 <a href="#">SPC</a> for brand-specific information.</p> <p>If a dose is missed then the next scheduled dose should be taken as usual; <u>a double dose should not be taken to make up for a missed dose.</u></p>
Other important information:	<p>Methylphenidate is a schedule 2 controlled drug and is subject to <a href="#">legal prescription requirements</a>. It has the potential for misuse and diversion.</p> <p>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.</p> <p>Alcohol may exacerbate CNS adverse effects of methylphenidate and should be avoided during use.</p> <p>Methylphenidate may cause false positive laboratory test results for amphetamines.</p>
<p><b>7. Significant medicine interactions</b> <span style="float: right;"><a href="#">Back to top</a></span></p> <p>The following list is not exhaustive. Please see <a href="#">BNF</a> or <a href="#">SPC</a> for comprehensive information and recommended management.</p> <ul style="list-style-type: none"> <li>• <b>Monoamine oxidase inhibitors (MAOIs):</b> risk of hypertensive crisis. The combination should be avoided, and use of methylphenidate and MAOIs should be separated by at least 14 days</li> </ul>	

- **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:** risk of additive effects (e.g. linezolid)
- **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)
- **Apraclonidine:** effects decreased by methylphenidate.
- **Carbamazepine:** may decrease methylphenidate levels
- **Ozanimod:** may increase risk of hypertensive crisis

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

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The GP completes the following referral form <https://www.berkshirehealthcare.nhs.uk/media/109514410/adhd-clinic-shared-care-actions-form.pdf> (See Section 17) which includes providing baseline investigations. Review of 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 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
- Risk assessment for substance misuse and drug diversion
- Height, weight, and body mass index (BMI)
- Blood pressure (BP) and heart rate
- Arrange for electrocardiogram (ECG), only 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
  - Chest pain suggestive of cardiac origin
  - Signs of heart failure, heart murmur or hypertension
  - Current treatment with a medicine that may increase cardiac risk

### Initial monitoring:

- Before every change of dose: assess heart rate, blood pressure.
- 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.
- 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 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. 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.



## 9. Ongoing monitoring requirements to be undertaken by primary care

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See [section 10](#) for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
<ul style="list-style-type: none"> <li>Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms</li> <li>Weight and appetite</li> <li>Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder)</li> <li>Explore whether patient is experiencing any difficulties with sleep</li> </ul>	Every 6 months, and after any change of dose recommended by specialist team.
<ul style="list-style-type: none"> <li>Assessment of adherence, and for any indication of methylphenidate abuse, misuse, or diversion</li> </ul>	As required, based on the patient's needs and individual circumstances
<ul style="list-style-type: none"> <li>Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD</li> </ul>	Annually

**(If relevant) 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

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**Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)**

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

Result	Action for primary care
<p><b>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.</b></p>	
<p><b>Cardiovascular</b> Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP</p>	<ul style="list-style-type: none"> <li>In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management</li> <li>In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.</li> </ul>
<p><b>Weight or BMI outside healthy range</b>, anorexia or weight loss</p>	<p>Exclude other reasons for weight loss. Give advice as per <a href="#">NICE NG87</a>:</p> <ul style="list-style-type: none"> <li>take medication with or after food, not before</li> <li>additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off</li> <li>obtaining dietary advice</li> <li>consuming high-calorie foods of good nutritional value</li> </ul>

	Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
<b>Haematological disorders</b> 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.
<b>Psychiatric disorders</b> 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.
<b>Nervous system disorders</b> 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
<b>New or worsening seizures</b>	Discontinue methylphenidate. Discuss with specialist team.
<b>Symptoms of serotonin syndrome</b> 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.
<b>Insomnia or other sleep disturbance</b>	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.
<b>Suspicion of abuse, misuse, or diversion</b>	Discuss with specialist team

## 11. Advice to patients and carers

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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 or medicines affect their ability to drive safely. See <https://www.gov.uk/adhd-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/>

## 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. Clinicians should be aware that patients may have other risk factors which independently alter the risks.

Specialists will provide specialist advice to primary care if the patient becomes or plans to become pregnant and wishes to continue medication. ADHD medication is not recommended to continue unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy (See SmPC).

Healthcare professional information available from:

<https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-METHYLPHENIDATE-IN-PREGNANCY/>

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

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- Erleigh Road Clinic: [Neuropsychology@berkshire.nhs.uk](mailto:Neuropsychology@berkshire.nhs.uk) / 0118 929 6477/6472, though this is a very small service and cannot guarantee an urgent response.
- Common Point of Entry (CPE): Berkshire Healthcare NHS Foundation Trust 2nd Floor, The Old Forge 45-47 Peach Street Wokingham RG40 1XJ Phone number 0300 365 2000 (Press option 4)

- Medicines Information Service at Prospect Park Hospital via 0118 960 5075 between 9am and 1pm on weekdays or via email: [medicines.information@berkshire.nhs.uk](mailto:medicines.information@berkshire.nhs.uk)

## 14. Additional information

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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

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- Methylphenidate hydrochloride 5 mg tablets (Medikinet®). Date of revision of the text 29/01/2021. Accessed via <https://www.medicines.org.uk/emc/product/328/smpc>
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- Specialist Pharmacy Service. Methylphenidate Lactation Safety Information. Last updated September 2018. Accessed via <https://www.sps.nhs.uk/medicines/methylphenidate/> on 05/05/2021

## 16. Other relevant national guidance

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- 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

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

### To be agreed and completed locally

The Berkshire Healthcare Adult ADHD Service operates solely for patients of GPs who have agreed Shared Care in advance, which is part of the initial referral process. Patients cannot be accepted for medication where there is not a GP agreeing to ongoing prescribing, since this is outside the remit of the service, and would divert resources from seeing new patients. Patients can be seen for diagnosis only.

The service provides: diagnostic (re)assessment for ADHD, initiation and titration of ADHD medication and yearly\* reviews of the efficacy and necessity of ongoing ADHD treatment.

\*The Service now offer a mixed model with remote appointments and aim to review patients within 2 years. If the patient requires an earlier review, GPs may contact the Service for advice. In East Berkshire, there is a scheme for GPs to carry out structured annual ADHD reviews. Frimley ICB have provided additional training to support this.

The service does not offer an ongoing prescribing or monitoring function and cannot provide urgent mental health input.

### Referral Process

#### **STEP 1: GP to send initial referral request for Diagnostic Assessment to Common Point of Entry (CPE), including patient details and brief summary of concerns.**

Once a referral is received, the service will perform an initial screen and add the patients name to the waiting list for an appointment. The patient is then seen for an ADHD assessment (for diagnosis, pending medical assessment).

#### **STEP 2: Secondary Care Medical ADHD Assessment**

Assessment includes physical health, mental health, social circumstances (including past and present medical and psychiatric disorders or symptoms), concomitant medicines and history or risk of substance misuse.

#### **STEP 3: A request is sent to the patients General Practitioner to complete Shared Care Actions (SCA) Form, available at:**

<https://www.berkshirehealthcare.nhs.uk/media/109514410/adhd-clinic-shared-care-actions-form.pdf>

Full history and details of any diagnosis or history where caution is needed for potential medication treatment, including

- Assessment of history of exercise syncope, undue breathlessness and other cardiovascular symptoms
- Past and present medical and psychiatric symptoms
- Physical assessment, including cardiovascular system examination, weight, blood pressure and heart rate
- If there is past medical or family history of serious cardiac disease, a history of sudden death in young family members or abnormal findings on previous cardiac examination, then provide ECG details with interpretation (consult a cardiologist for clarification as needed).
- Risk assessment for substance misuse and drug diversion.
- Provide details of current medication.

#### **STEP 4: First Prescribing Appointment with Specialist**

1. Review SCA form from GP
2. Review patient in line with Section 8. NB NICE advise; 'that an ECG is not needed before starting stimulants, atomoxetine or guanfacine if cardiovascular history and examination are normal and the person is not on medicine that poses an increased cardiovascular risk.'
3. Provide the initial FP10 prescription for the medication of choice (unless the patient is already receiving prescriptions from GP).

#### **STEP 5: Follow-up with Specialist**

4. Within 4 weeks of initial prescription (and usually within first 2 weeks)
  - review efficiency of the prescribed ADHD drug
  - monitor for side effects and document any problems discussed
  - adjust dose if necessary and correspond with GP as necessary for sharing of information
  - take pulse and blood pressure
5. Continue prescribing until patient is stabilised
6. Once the patient is stable, transfer to GP care for continuation of treatment.
7. The patient will be invited back to the specialist for a review (unless this need is being met by a GP choosing to participate in the East Berkshire enhanced Shared Care scheme). The Service now offer a mixed model with remote appointments and aim to review patients within 2 years. If the patient requires an earlier review, GPs may contact the Service for advice. Patients who do not attend their review appointment will have their name removed from the review list and the GP will be informed.  
 Note: The patient will only be open to the Specialist Service for the time medicines are being initiated and at the time of the review appointment. It is not possible to keep the patient 'open' on the Adult ADHD Clinic List at other times as referrals to other services would be delayed should they become necessary.
8. Review progress if requested by GP - change in behaviour, treatment resistance, increased sedation, etc. Notify the GP of the results of any patient reviews, including changes in prescribed dose. Ensure the patient has sufficient medication until the GP has received this information, at least 14 days.
9. Receive and respond to feedback from GP as appropriate, e.g. progress/status of the patient and in particular noting any dose changes/alterations/discontinuation etc. of treatment under the agreement.

#### **STEP 6: General Practitioner Responsibilities – Maintenance (See Section 9)**