Effective Shared Care Agreement (ESCA)

Methylphenidate (from age 6 years)

Approved for Solihull locality only.

ESCA: For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Methylphenidate in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Attention-Deficit/Hyperactivity Disorder (ADHD) are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary
2. Specialist assessment and confirmation of the diagnosis of attention deficit/hyperactivity disorder
3. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
4. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made
5. Do baseline monitoring prior to initiation of this agent: • weight, blood pressure, pulse and essential medical history, cardiovascular examination and ECG where indicated. • full mental health and social assessment, full history and physical examination, family history of cardiac disease and an ECG if there is past medical and/or family history of cardiac or cerebrovascular problems. • risk assessment for substance misuse and potential for drug diversion.
6. Initiate treatment and stabilise dose of methylphenidate
7. Methylphenidate is a Schedule 2 Controlled Drug (CD, therefore should be prescribed in line with the Misuse of Drug Regulations.). Prescription requirements for prescribing CDs should therefore be observed, maximum of 30 day per prescription.
8. Advise the patient on the importance of good adherence with the prescribed medication. Check adherence at each clinic appointment
9. Review the patient's condition and response to treatment every 6 months. Advise patients, families/ carers to report any side effects and/ or concerns. At 6 monthly reviews (unless otherwise indicated): • Monitor efficacy of long term treatment and consider whether benefit can be gained from continued treatment. • Monitor height, weight, appetite, heart rate and BP and any psychiatric symptoms • Request any further investigations that are clinically indicated such as ECG, blood investigations • Assess progress with regards to psychological, behavioural, educational and occupational needs • Assess ongoing need for medication • Assess any side effects • Consider the potential for drug diversion and potential for misuse
10. Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
11. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
12. Advise the GP what to do when defined parameters are altered, and when (if at all) an emergency referral should be made back to the specialist service.
13. Advise GP on the management of side effects and raise awareness at which point these will be reviewed and/ or managed by the specialist.
14. Advise the GP when to stop treatment and on management of discontinuation if necessary.
15. Report serious adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
16. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1)

General Practitioner responsibilities
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days
2. Ensure: • Patient/ family are clear who will be responsible for monitoring and what this will entail. • Patient/ family are aware of any significant adverse effects/ events, which should be urgently reported and who these should be reported to. (GP/ specialist)
3. Prescribe methylphenidate at the dose recommended. If using modified release preparation, please prescribe by BRAND name.
4. Adjust the dose as advised by the specialist.
5. Methylphenidate is a Schedule 2 Controlled Drug (CD, therefore should be prescribed in line with the Misuse of Drug Regulations.). Prescription requirements for prescribing CDs should therefore be observed, maximum of 30 day per prescription.
6. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care

7. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist
8. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment
9. Refer back to specialist if condition deteriorates
10. For women of child bearing age, refer prescribing responsibilities back to specialist immediately if patient becomes, or wishes to become, pregnant.
11. Report serious adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk
12. Stop treatment on advice of specialist

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2. Attend regularly for required blood tests and annual health checks.
3. Share any concerns in relation to treatment with Methylphenidate with the specialist, clinical nurse specialist or GP
4. Report any adverse effects to the specialist or GP whilst taking Methylphenidate
5. Attend regular outpatient appointments with the specialist
6. Inform the specialist, clinical nurse specialist or GP if she becomes or wishes to become pregnant.

Please enter Specialist contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

Agent + Form	Medikinet Tablets	Equasym XL modified-release capsules	Medikinet XL modified-release capsules	Concerta XL prolonged-release tablets	Xenidate XL	Xaggitin XL
Strength and cost	5 mg = £3.03 (30) 10 mg = £5.49 (30) 20 mg = £10.92 (30)	10mg = £25.00 (30) 20mg =£30.00 (30) 30mg = £35.00 (30)	5mg = £24.04 (30) 10mg = £24.04 (30) 20mg = £28.86 (30) 30mg = £33.66 (30) 54mg = £57.72 (30)	18mg = £31.19 (30) 27mg = £31.81 (30) 36mg = £42.45 (30) 54mg = £73.62 (30)	18mg=£20.27 (30) 27mg=£23.93 (30) 36mg =£27.59 (30) 54mg =£47.85 (30)	18mg=£15.58 (30) 27mg=£18.40 (30) 36mg =£21.22 (30) 54mg =£36.80 (30)
Indication	Attention-Deficit/Hyperactivity Disorder (ADHD) • Methylphenidate is indicated as part of a comprehensive treatment programme for Attention Deficit Hyperactivity Disorder (ADHD in children aged 6 years of age and over when remedial measures alone prove insufficient. • Treatment must be under the supervision of a specialist in childhood behavioural disorders. • Diagnosis should be made according to DSM 5 criteria or the guidelines in ICD-10 and should be based on a complete history and evaluation of the patient. Diagnosis cannot be made solely on the presence of one or more symptoms. • The specific aetiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and specialised psychological, educational, and social resources. • A comprehensive treatment programme typically includes psychological, educational and social measures as well as pharmacotherapy and is aimed at stabilising children with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity, minor neurological signs and abnormal EEG. Learning may or may not be impaired. • Methylphenidate treatment is not indicated in all children with ADHD and the decision to use the drug must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age. Appropriate educational placement is essential, and psychosocial intervention is generally necessary. Where remedial measures alone prove insufficient, the decision to prescribe a stimulant must be based on rigorous assessment of the severity of the child's symptoms. The use of methylphenidate should always be used in this way according to the licensed indication and according to prescribing / diagnostic guidelines.					
	Careful dose titration is necessary at the start of treatment with methylphenidate Dose titration should be started at the lowest possible dose. This is normally achieved using an immediate release formulation taken in divided doses.					
	Medikinet Tablets	**Equasym XL modified-release capsules**	**Medikinet XL modified-release capsules**	**Concerta XL prolonged-release tablets**	**Xenidate XL**	**Xaggitin XL**
Dose	The recommended starting daily dose is 5 mg once daily or twice daily (e.g. at breakfast and lunch), increasing if necessary by weekly increments of 5-10 mg in the daily dose according to tolerability and degree of efficacy observed. The total daily dose should be administered in divided doses			The recommended starting dose of methylphenidate prolonged-release tablets for patients who are not currently taking methylphenidate, or for patients who are on stimulants other than methylphenidate, is 18 mg once daily.		
		Methylphenidate XL 10 mg once daily may be used in place of immediate release methylphenidate hydrochloride 5 mg twice daily from the beginning of treatment where the treating physician considers that twice daily dosing is appropriate from the outset and twice daily treatment administration is impracticable.				
Maximum daily dosage	60mg.	60 mg	60 mg.	54mg.	54 mg	54 mg
Patients New to Methylphenidate				Clinical experience with methylphenidate XL/prolonged-release tablets is limited in these patients. Methylphenidate XL/prolonged-release tablets may not be indicated in all children with ADHD syndrome.		

<table>
<tr><th></th><th>Medikinet Tablets</th><th>Equasym XL modified-release capsules</th><th>Medikinet XL modified-release capsules</th><th>Concerta XL prolonged-release tablets</th><th>Xenidate XL</th><th>Xaggitin XL</th></tr>
<tr><td>Patients Currently Using Methylphenidate</td><td></td><td colspan="2">Patients established on an immediate release methylphenidate hydrochloride formulation may be switched to the milligram equivalent daily dose of Methylphenidate XL</td><td colspan="3">The recommended dose of methylphenidate XL/prolonged-release tablets for patients who are currently taking methylphenidate three times daily at doses of 15 to 45 mg/day is provided in Table 1. Dosing recommendations are based on current dose regimen and clinical judgement
TABLE 1
Recommended Dose Conversion from Other Methylphenidate Hydrochloride Regimens, where available, to modified release preparations:<table><tr><th>Previous Methylphenidate Hydrochloride Daily Dose</th><th>Recommended modified release preparations dose</th></tr><tr><td>5 mg Methylphenidate three times daily</td><td>18 mg once daily</td></tr><tr><td>10 mg Methylphenidate three times daily</td><td>36 mg once daily</td></tr><tr><td>15 mg Methylphenidate three times daily</td><td>54 mg once daily</td></tr></table>If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued</td></tr>
<tr><td>Renal Impairment</td><td colspan="6" rowspan="2">There is no experience with the use of methylphenidate in patients with renal or hepatic insufficiency. Caution should be exercised in these patients.</td></tr>
<tr><td>Hepatic impairment</td></tr>
<tr><td>Contraindications</td><td colspan="6">• Hypersensitivity to methylphenidate or to any of the excipients listed
• 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, 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)
• Pre-existing cardiovascular disorders including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels)
• Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke
• In addition for Medikinet XL - a history of pronounced anacidity of the stomach with a pH value above 5.5, in therapy with H2 receptor blockers or in antacid therapy</td></tr>
<tr><td>Cautions</td><td colspan="6">Methylphenidate treatment is not indicated in all children with ADHD and the decision to use the drug must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age.
Long-term use (more than 12 months) in children and adolescents
The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials. Methylphenidate treatment should not and need not, be indefinite. Methylphenidate treatment is usually discontinued during or after puberty. Patients on long-term therapy (i.e. over 12 months) must have careful ongoing monitoring according to the guidance listed in the monitoring section for cardiovascular status, growth, appetite, development of de novo or worsening of pre-existing psychiatric disorders. Psychiatric disorders to monitor for are described below, and include (but are not limited to) motor or vocal tics, aggressive or hostile behaviour, agitation, anxiety, depression, psychosis, mania, delusions, irritability, lack of spontaneity, withdrawal and excessive perseveration.
The physician who elects to use methylphenidate for extended periods (over 12 months) in children and adolescents with ADHD should periodically re-evaluate the long-term usefulness of the medicinal product for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy. It is recommended that methylphenidate is de-challenged at least once yearly to assess the child's condition (preferably during times of school holidays). Improvement may be sustained when the medicinal product is either temporarily or permanently discontinued.
<u>Use in the elderly</u>
Methylphenidate should not be used in the elderly. Safety and efficacy has not been established in this age group.
<u>Use in children under 6 years of age</u>
Methylphenidate should not be used in children under the age of 6 years. Safety and efficacy in this age group has not been established.
<u>Cardiovascular status</u>
Patients who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden cardiac or unexplained death or malignant arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further specialist cardiac evaluation if initial findings suggest such history or disease. Patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other symptoms suggestive of cardiac disease during methylphenidate treatment should undergo a prompt specialist cardiac evaluation. Cardiovascular status should be carefully monitored. Blood pressure and pulse should be recorded on a centile chart at each adjustment of dose and then at least every 6 months. The use of methylphenidate is contraindicated in certain pre-existing cardiovascular disorders unless specialist paediatric cardiac advice has been obtained.</td></tr>
</table>

Cautions	Sudden death and pre-existing structural cardiac abnormalities or other serious cardiac disorders Sudden death has been reported in association with the use of stimulants of the central nervous system at usual doses in children, 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 children or adolescents 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. Misuse and cardiovascular events Misuse of stimulants of the central nervous system may be associated with sudden death and other serious cardiovascular adverse events. Cerebrovascular disorders Patients with additional risk factors (such as a history of cardiovascular disease, concomitant medications that elevate blood pressure) should be assessed at every visit for neurological signs and symptoms after initiating treatment with methylphenidate. Cerebral vasculitis appears to be a very rare idiosyncratic reaction to methylphenidate exposure. There is little evidence to suggest that patients at higher risk can be identified and the initial onset of symptoms may be the first indication of an underlying clinical problem. Early diagnosis, based on a high index of suspicion, may allow the prompt withdrawal of methylphenidate and early treatment. The diagnosis should therefore be considered in any patient who develops new neurological symptoms that are consistent with cerebral ischemia during methylphenidate therapy. These symptoms could include severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory. Treatment with methylphenidate is not contraindicated in patients with hemiplegic cerebral palsy Psychiatric disorders Co-morbidity of psychiatric disorders in ADHD is common and should be taken into account when prescribing stimulant products. In the case of emergent psychiatric symptoms or exacerbation of pre-existing psychiatric disorders, methylphenidate should not be given unless the benefits outweigh the risks to the patient. Development or worsening of psychiatric disorders should be monitored at every adjustment of dose, then at least every 6 months, and at every visit: discontinuation of treatment may be appropriate. Exacerbation of pre-existing psychotic or manic symptoms In psychotic patients, administration of methylphenidate may exacerbate symptoms of behavioural disturbance and thought disorder. Emergence of new psychotic or manic symptoms Treatment-emergent psychotic symptoms (visual/tactile/auditory hallucinations and delusions) or mania in children and adolescents without prior history of psychotic illness or mania can be caused by methylphenidate at usual doses. If manic or psychotic symptoms occur, consideration should be given to a possible causal role for methylphenidate and discontinuation of treatment may be appropriate. Aggressive or hostile behaviour The emergence or worsening of aggression or hostility can be caused by treatment with stimulants. Patients treated with methylphenidate should be closely monitored for the emergence or worsening of aggressive behaviour or hostility at treatment initiation, at every dose adjustment and then least every 6 months and every visit. Physicians should evaluate the need for adjustment of the treatment regimen in patients experiencing behavioural changes bearing in mind that upwards or downwards titration may be appropriate. Treatment interruption can be considered. Suicidal tendency Patients with emergent suicidal ideation or behaviour during treatment for ADHD should be evaluated immediately by their physician. Consideration should be given to the exacerbation of an underlying psychiatric condition and to a possible causal role of methylphenidate treatment. Treatment of an underlying psychiatric condition may be necessary and consideration should be given to a possible discontinuation of methylphenidate. Tics Methylphenidate is associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported. Family history should be assessed and clinical evaluation for tics or Tourette's syndrome in children should precede use of methylphenidate. Patients should be regularly monitored for the emergence or worsening of tics during treatment with methylphenidate. Monitoring should be at every adjustment of dose and then at least every 6 months or every visit. Anxiety, agitation or tension Methylphenidate is associated with the worsening of pre-existing anxiety, agitation or tension. Clinical evaluation for anxiety, agitation or tension should precede use of methylphenidate and patients should be regularly monitored for the emergence or worsening of these symptoms during treatment, at every adjustment of dose and then at least every 6 months or every visit. Forms of bipolar disorder Particular care should be taken in using methylphenidate to treat ADHD in patients with co morbid bipolar disorder (including untreated type 1 bipolar disorder or other forms of bipolar disorder) because of concern for possible precipitation of a mixed/manic episode in such patients. Prior to initiating treatment with methylphenidate, patients with co morbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. Close ongoing monitoring is essential in these patients (see above 'Psychiatric Disorders' and section 4.2). Patients should be monitored for symptoms at every adjustment of dose, then at least every 6 months and at every visit. Growth Moderately reduced weight gain and growth retardation have been reported with long-term use of methylphenidate in children. The effects of methylphenidate on final height and final weight are currently unknown and being studied. Growth should be monitored during methylphenidate treatment: height, weight and appetite should be recorded at least 6 monthly with maintenance of a growth chart. Patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted. Seizures Methylphenidate should be used with caution in patients with epilepsy. Methylphenidate may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and rarely in patients without a history of convulsions and no EEG abnormalities. If seizure frequency increases or new-onset seizures occur, methylphenidate should be discontinued.

Cautions	Abuse, misuse and diversion Patients should be carefully monitored for the risk of diversion, misuse and abuse of methylphenidate. Methylphenidate should be used with caution in patients with known drug or alcohol dependency because of a potential for abuse, misuse or diversion. Chronic abuse of methylphenidate can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially in response to parenteral abuse. Patient age, the presence of risk factors for substance use disorder (such as co-morbid oppositional-defiant or conduct disorder and bipolar disorder), previous or current substance abuse should be taken in to account when deciding on a course of treatment for ADHD. Caution is called for in emotionally unstable patients, such as those with a history of drug or alcohol dependence, because such patients may increase the dosage on their own initiative. For some high-risk substance abuse patients, methylphenidate or other stimulants may not be suitable and non-stimulant treatment should be considered. Withdrawal Careful supervision is required during withdrawal, since this may unmask depression as well as chronic over-activity. Some patients may require long-term follow-up. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Fatigue Methylphenidate should not be used for the prevention or treatment of normal fatigue states. Drug screening This product contains methylphenidate which may induce a false positive laboratory test for amphetamines, particularly with immunoassay screen test. Renal or hepatic insufficiency There is no experience with the use of methylphenidate in patients with renal or hepatic insufficiency. Haematological effects The long-term safety of treatment with methylphenidate is not fully known. In the event of leukopenia, thrombocytopenia, anaemia or other alterations, including those indicative of serious renal or hepatic disorders, discontinuation of treatment should be considered.

<table>
<tr><td rowspan="6">Cautions</td><td rowspan="2">Use in adults</td><td>Medikinet Tablets</td><td>Equasym XL modified-release capsules</td><td>Medikinet XL modified-release capsules</td><td>Concerta XL prolonged-release tablets</td><td>Xenidate XL</td><td>Xaggitin XL</td></tr>
<tr><td colspan="2">Methylphenidate is not licensed for use in adults with ADHD. Safety and efficacy have not yet been established in this age group.</td><td colspan="3">In adolescents whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. However, start of treatment with methylphenidate prolonged-release tablets in adults is not appropriate</td><td>Safety and efficacy have not been established for the initiation of treatment in adults or the routine continuation of treatment beyond 18 years of age. If treatment withdrawal has not been successful when an adolescent has reached 18 years of age continued treatment into adulthood may be necessary. The need for further treatment of these adults should be reviewed regularly and undertaken annually.</td></tr>
<tr><td colspan="6">Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary</td></tr>
<tr><td colspan="2">Medikinet Tablets</td><td>Equasym XL modified-release capsules</td><td>Medikinet XL modified-release capsules</td><td>Concerta XL prolonged-release tablets</td><td>Xenidate XL</td><td>Xaggitin XL</td></tr>
<tr><td colspan="3"></td><td>Because the methylphenidate XL tablet is nondeformable and does not appreciably change in shape in the gastrointestinal (GI) tract, it should not ordinarily be administered to patients with pre-existing severe GI narrowing (pathologic or iatrogenic) or in patients with dysphagia or significant difficulty in swallowing tablets. There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of drugs in nondeformable prolonged-release formulations.</td><td colspan="2"></td></tr>
<tr><td colspan="2">The tablets should be swallowed whole or divided into halves with the aid of liquids, either with meals or after meals.</td><td colspan="2">The capsules may be swallowed whole with the aid of liquids, or alternatively, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce (EquasymXL & Medikinet XL) or yoghurt (Medikinet) and given immediately, and not stored for future use. Drinking some fluids, e.g. water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed.</td><td colspan="3">Due to the prolonged-release design of the tablet, methylphenidate XL should only be used in patients who are able to swallow the tablet whole.
Patients should be informed that methylphenidate XL must be swallowed whole with sufficient liquid.
Tablets must not be chewed, divided, or crushed</td></tr>
<tr><td rowspan="2">Side Effects</td><td>Very common</td><td colspan="6">Medikinet/Equasym XL/ Medikinet XL/ Concerta XL/ Xenidate XL/ Xaggitin XL
Insomnia, nervousness, headache</td></tr>
<tr><td>Common</td><td colspan="3">Medikinet/Equasym XL/ Medikinet XL/ Concerta XL/ Xenidate XL/ Xaggitin XL
Nasopharyngitis, anorexia, decreased appetite, moderately reduced weight and height gain during prolonged use in children, affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, dizziness, dyskinesia, psychomotor hyperactivity, somnolence, arrhythmia, tachycardia, palpitations, hypertension, cough, pharyngolaryngeal pain, abdominal pain, diarrhoea, nausea, stomach discomfort and vomiting, dry mouth, alopecia, pruritus, rash, urticarial, arthralgia, pyrexia, growth retardation during prolonged use in children, changes in blood pressure and heart rate (usually an increase), weight decreased</td><td colspan="3">In addition
Equasym XL - Bruxism
Concerta XL/Xenidate XL/Xaggitin XL –
Upper respiratory tract infection, Sinusitis, Mood swings, Tics, Initial insomnia, Depressed mood, Libido decreased, Tension, Bruxism, Panic attack, paresthaesia, Tension headache, accommodation disorder, vertigo. Alanine aminotransferase increased. Muscle tightness, Muscle spasms, erectile dysfunction, fatigue, irritability, feeling jittery, asthenia, thirst</td></tr>
</table>

Monitoring	Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders Patients should be monitored for the risk of diversion, misuse and abuse of methylphenidate
Pre-treatment screening:	Prior to prescribing, it is necessary to conduct a baseline evaluation of a patient's cardiovascular status including blood pressure and heart rate. A comprehensive history should document concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death and accurate recording of pre-treatment height and weight on a growth chart
Ongoing monitoring:	Growth, psychiatric and cardiovascular status should be continuously monitored. • Blood pressure and pulse should be recorded on a centile chart at each adjustment of dose and then at least every 6 months; • Height, weight and appetite should be recorded at least 6 monthly with maintenance of a growth chart; • Development of de novo or worsening of pre-existing psychiatric disorders should be monitored at every adjustment of dose and then at least every 6 months and at every visit.

Parameter	**By Specialist**	**By GP**
Height and weight	Baseline and @6 months (or before discharge) including keeping a growth chart	6 monthly after discharge from specialist.
Appetite	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.
Heart rate and BP	Baseline and @6 months (or before discharge) and before and after each dose change	6 monthly after discharge from specialist.
Psychiatric assessments	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.
Risk of diversion or abuse	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.

Long-term (more than 12 months) use in children and adolescents	• The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials. • Methylphenidate treatment should not and need not, be indefinite. Methylphenidate treatment is usually discontinued during or after puberty. • The physician who elects to use methylphenidate for extended periods (over 12 months) in children and adolescents with ADHD should periodically re-evaluate the long-term usefulness of the medicinal product for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy. • It is recommended that methylphenidate is de-challenged at least once yearly to assess the child's condition (preferable during times of school holidays). Improvement may be sustained when the medicinal product is either temporarily or permanently discontinued.
Dose reduction and discontinuation	Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a one-month period. If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued.

Drug Interactions (significant interaction as outlined in BNF, please see BNF and SPC for more detail)

Methylphenidate has the following interaction information:

Interacting agent	**Severity of interaction**	**Evidence for interaction**	**Notes**
Apraclonidine	Severe	Theoretical	Methylphenidate is predicted to decrease the effects of apraclonidine. Manufacturer advises avoid.
Isocarboxazid	Severe	Theoretical	Methylphenidate is predicted to increase the risk of a hypertensive crisis when given with isocarboxazid. Manufacturer advises avoid and for 14 days after stopping the MAOI.
Linezolid	Severe	Theoretical	Methylphenidate is predicted to increase the risk of elevated blood pressure when given with linezolid. Manufacturer advises avoid.
Moclobemide	Severe	Theoretical	Methylphenidate is predicted to increase the risk of a hypertensive crisis when given with moclobemide.
Phenelzine	Severe	Theoretical	Methylphenidate is predicted to increase the risk of a hypertensive crisis when given with phenelzine. Manufacturer advises avoid and for 14 days after stopping the MAOI.
Rasagiline	Severe	Theoretical	Rasagiline is predicted to increase the risk of a hypertensive crisis when given with methylphenidate. Manufacturer advises avoid.
Selegiline	Severe	Theoretical	Selegiline is predicted to increase the risk of a hypertensive crisis when given with methylphenidate. Manufacturer advises avoid.
Tranylcypromine	Severe	Theoretical	Methylphenidate is predicted to increase the risk of a hypertensive crisis when given with tranylcypromine. Manufacturer advises avoid and for 14 days after stopping the MAOI.

References

1. NICE TA98 - Methylphenidate, atomoxetine and dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents
2. NICE CG72 - Attention deficit hyperactivity disorder: diagnosis and management
3. SPC Ritalin tablet, Medikinet Tablets, Equasym XL modified-release capsules, Medikinet XL modified-release capsules, Concerta XL prolonged-release tablets, Matoride XL Prolonged-release Tablets and Xenidate XL, Delmosart Prolonged-release Tablets, Xaggitin XL
4. BNF

Monitoring Parameters- Maintenance therapy

If the patient returns to the specialist services within a 6 month period, the monitoring should be continued within the specialist services. For treatment periods greater than 6 month continued monitoring can be agreed with the GP service as appropriate.

Methylphenidate

Parameter	By Specialist	By GP
Height and weight	Baseline and @6 months (or before discharge) including keeping a growth chart	6 monthly after discharge from specialist.
Appetite	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.
Heart rate and BP	Baseline and @6 months (or before discharge) and before and after each dose change	6 monthly after discharge from specialist.
Psychiatric assessments	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.
Risk of diversion or abuse	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.

Please note:

Children/adolescents who are not growing or gaining height and weight as expected may need to have their treatment interrupted. This should involve discussions with the specialist

Medication profile

Medication to be TRANSFERRED TO GP PRESCRIBING		
Drug name and form (NB Brand name prescribing essential)	**Dose and frequency**	**Commence on:**

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist:				
Specialist nurse				

Appendix 1:

Effective Shared Care Agreement (ESCA)
Methylphenidate (from age 6 years)
Approved for Solihull CCG only.

For the treatment of attention deficit hyperactivity disorder

Please refer to BSSE APC formulary website for complete document.

Agent	Tick	Dose		Agent	Tick	Dose
Medikinet Tablets				**Concerta XL prolonged-release tablets**		
Medikinet XL modified-release capsules				**Xenidate XL**		
Equasym XL modified-release capsules				**Xaggitin XL**		

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Transitioning patients Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary	Adult service consultant to tick and sign please

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the below named patient with Methylphenidate in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme

General Practitioner
Name (please print)_____Signature _____Date_____

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.

In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care