

Methylphenidate for ADHD Children and Young People

**Part of the shared care protocol for ADHD in Children and Young People
Traffic light classification- Amber 1
Information sheet for Primary Care Prescribers**

Indications

Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 to 17 who are under the care of a specialist (Consultant Psychiatrist, Community Paediatrician or Non-Medical Prescriber specializing in ADHD) as part of a comprehensive treatment program¹ – licensed indication.

Any patient groups to be excluded from this shared care:

Patients ≥ 18 years old – see separate Nottinghamshire APC shared care protocol and medication information sheets for adult ADHD

Children < 6 years old – unlicensed, not recommended by NICE

Therapeutic Summary

Methylphenidate is a treatment option recommended by NICE for the management of ADHD in children and young people. It is usually used for ADHD where there is no significant co-morbidity or for ADHD with co-morbid oppositional defiant disorder (ODD) or conduct disorder¹.

It is a CNS stimulant, although the precise mechanism of action by which it works on ADHD is unknown. Following titration and dose stabilization, prescribing and monitoring should be carried out under locally agreed shared care arrangements with primary care¹.

Medicines Initiation

Treatment with methylphenidate should only be initiated by a specialist with expertise in ADHD following a comprehensive assessment and diagnosis¹. GPs may continue prescribing and monitoring medication treatment under shared care arrangements¹.

Products available^{2,3}

Please refer to the [Nottinghamshire Joint Formulary](#) for guidance on preferred brand prescribing.

Immediate release

- Generic methylphenidate immediate-release tablets – 5mg, 10mg and 20mg. Cost x 30 tablets = £3.03, £3.99 and £10.92 respectively.
- Ritalin[®] 10mg immediate-release tablets. Cost x 30 tablets = £6.68.
- Medikinet[®] immediate-release tablets – 5mg, 10mg and 20mg. Cost x 30 tablets = £3.03, £5.49 and £10.92 respectively.

Modified release

- *Delmosart*[®] - 18mg, 27mg, 36mg and 54mg modified-release tablets. Cost x 30 tablets = £15.57, £18.39, £21.21 and £36.79 respectively.
- *Xaggitin XL*[®] - 18mg, 27mg, 36mg and 54mg modified-release tablets. Cost x 30 tablets = £15.58, £18.40, £21.22 and £36.80 respectively.
- *Xenidate XL*[®] - 18mg, 27mg, 36mg and 54mg modified-release tablets. Cost x 30 tablets = £15.57, £18.39, £21.21 and £36.79 respectively.

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- *Concerta XL*[®] - 18mg, 27mg, 36mg and 54mg modified-release tablets. Cost x 30 tablets = £31.19, £36.81, £42.45 and £73.62. Branded generics are now available e.g. Delmosart[®], Xenidate XL[®], Xaggitin XL[®].
- *Equasym XL*[®] - 10mg, 20mg and 30mg modified-release capsules. Cost x 30 capsules = £25.00, £30.00 and £35.00 respectively.
- *Medikinet XL*[®] - 5mg, 10mg, 20mg, 30mg, 40mg, 50mg and 60mg modified-release capsules. Cost x 30 capsules = £24.04, £24.04, £28.86, £33.66, £57.72, £62.52 and £67.32 respectively.
- *Ritalin XL*[®] - 10mg, 20mg, 30mg, 40mg and 60mg modified-release capsules = £23.92, £28.72, £33.49, £57.43 and £66.98 respectively

To avoid confusion, modified-release preparations should be prescribed by brand name.

Different branded modified-release methylphenidate formulations have different pharmacokinetic profiles e.g. immediate vs. modified/sustained release so it is important that the formulation/brand is always specified in the prescription.

Immediate release formulations do not need to be prescribed by brand name.

N.B. The contents of *Equasym XL*[®] capsules, and *Medikinet XL*[®] capsules can be sprinkled on a tablespoon of soft food (e.g. apple sauce or yoghurt), then swallowed immediately without chewing.^{6,7}

Methylphenidate is a Schedule 2 Controlled Drug (CD). As such, prescriptions must conform to specific CD prescription writing criteria and each prescription should be for no longer than 30 days treatment.

Dosages and route of administration

- Initiation, titration and stabilisation of dose will be determined and performed by the specialist.
- The immediate-release methylphenidate formulation may be used, but simple medication regimens are often preferred (e.g. once daily morning dose of a modified-release preparation).
- The dose will be increased gradually until there is no further improvement in symptoms, behaviour, education and/or relationships and side effects are tolerable.
- Titration usually takes 4-6 weeks, but may be slower if tics, seizures or other co-morbidities are present.¹

Dosage may be altered by specialists to reflect the child's current physical condition, symptoms or social demands. The patient should require no extra monitoring than already described in this guidance if dosage is adjusted by the specialist in this way.

As a child grows, the dose of methylphenidate will need to be amended to ensure the treatment remains at steady state. A patient's weight and height should be monitored as described under "Ongoing monitoring", and dosage may be increased if required as per the section above; "dosage and route of administration". Increases in medication dose due to growth of the patient should be viewed as a patient's treatment being "stable".

Where a patient has been switched between medications (i.e. methylphenidate to atomoxetine or vice-versa) further monitoring may be required, as per specialist instruction.

Modified-release methylphenidate:

Delmosart[®] (or Concerta XL[®]) is a prolonged-release form of methylphenidate (22% IR / 78% PR) administered once daily in the morning, formulated to replace three times daily dosing with the immediate-release formulation. Concerta XL has the longest duration of the modified-release preparations lasting between 8 to 12 hours. The dose may be adjusted in 9mg or 18 mg increments, from an initial dose of 18mg once daily (equivalent to 15mg daily immediate-release),

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to a maximum of 54 mg/day at approximately weekly intervals. Although 54mg/day is the maximum licensed dose (equivalent to 45mg/day of immediate release methylphenidate), the dose may be increased up to 2.1mg/kg daily (max. 108mg/day) under the direction of a specialist.

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

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

Immediate-release methylphenidate:

The usual starting regimen for immediate-release methylphenidate formulations is 5mg once or twice daily (e.g. morning and noon), which can be increased at weekly intervals by 5-10mg, up to 60mg daily in 2-3 divided doses (morning, noon and afternoon). Increasing the total daily dose of immediate-release methylphenidate to 2.1mg/kg/day (max. 90mg/day (adolescents) may occasionally be undertaken by a specialist in cases of poor response to medication treatment.

Doses of methylphenidate above 60mg/day (Concerta XL 54mg/day) are unlicensed and patients should be closely monitored for side-effects during the titration period.

Duration of treatment

Following an adequate treatment response, medication treatment for ADHD should be continued for as long as it remains clinically effective. This should be reviewed at least annually by the specialist.¹

In adolescents whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood². It is the specialist's responsibility to transfer care to the appropriate adult service if ADHD treatment is deemed appropriate to continue into adulthood. See the Nottinghamshire Area Prescribing Committee shared care protocol and medication information leaflets for adult ADHD at:

<https://www.nottsapc.nhs.uk/shared-care/>.

Monitoring Requirements and Responsibilities

Pre-treatment assessment to be performed by specialist and will include: diagnostic interview (e.g. DIVA), behavioral rating scales (e.g. SDQ, Conners', CAARS self and observer report), descriptive reports from parents and teachers, medical history and physical examination including heart rate, blood pressure, height, weight and appetite as a baseline.

For children where there is a first degree relative who has suffered from severe cardiac disease (e.g. myocardial infarction, arrhythmia) or sudden death of unknown cause before the age of 40 years, or in children who have a history of cardiac disease themselves, these patients should have further cardiac screening in the form of an ECG and echocardiogram. Cardiology expertise may be required in deciding if it is safe to start medication.

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Ongoing monitoring – monitoring will be performed monthly by the specialist for the first 3 months. Further physical monitoring will be performed by primary care (see below) and the results sent to the specialist for recording in the patients notes. Ongoing psychological response and assessment of continued need for methylphenidate will be performed by the specialist at 3 months and at 6 months and then at least annually.

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

Ongoing monitoring ¹	Frequency ¹
Heart Rate and Blood Pressure	Six monthly. Also before and after each dose change (note that increases in dose due to growth should be viewed as a patient being “stable” on their medication, and should require no extra monitoring). Compare with previous measurements. Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website . ¹⁰
Weight and appetite	Following initiation, at three months and six months, then: <ul style="list-style-type: none"> • Every 3 months in children 10 years and under. • Every 6 months in children over 10 years and young people Plot on a growth chart (link: http://www.rcpch.ac.uk/growthcharts). If weight loss or reduced weight gain this should be discussed with the specialist.
Height	Six monthly. Plot on a growth chart. If growth is affected significantly this should be discussed with the specialist.
Medication related side-effects*	At each visit.
Risk of diversion, misuse/abuse	At each visit
ECG, LFTs, FBC	Not recommended unless there is a clinical indication.

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

Explicit criteria for review and discontinuation of the medicine^{1,2,4,5,6,7}

Sustained resting tachycardia	Withhold/reduce dose, discuss with specialist team, with cardiology input if necessary.
Arrhythmia	Withhold/reduce dose, discuss with specialist team, with cardiology input if necessary.
Systolic blood pressure >95 th percentile (or clinically significant increase) Take three measurements (with	Withhold/reduce dose, discuss with specialist team, with cardiology input if necessary.

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appropriate cuff) within 10 minutes, patient at rest	
Failure to attend for physical monitoring	Do not issue further prescriptions, discuss as soon as possible with specialist
Exertional chest pain, unexplained syncope or dyspnoea	Withhold or reduce dose and discuss with specialist team, with prompt cardiology input if necessary.
Tics	Tics are commonly co-morbid with ADHD and usually unrelated to methylphenidate. Discuss with specialist if tics are new or significantly impairing function. Observation over a period of 3 months may be required before a clinical decision can be made. Dose reduction or switch to atomoxetine may be considered.
Insomnia and / or reduced appetite	Discuss with specialist team. May respond to dose reduction or timing adjustment
Psychotic symptoms (delusions, hallucinations)	Withhold and discuss with specialist team.
Anxiety symptoms, including panic	Discuss with specialist team.
Emergence of worsening of aggressive behaviour or hostility	Discuss with specialist team.
Priapism	Patients should be advised to seek immediate medical treatment if this rare side-effect should occur.
Anaemia related symptoms (e.g. paleness, lethargy)	Seek immediate medical attention, rarely related to methylphenidate.
Abnormal bruising / bleeding / severe sore throat / skin lesions or severe infection	Seek immediate medical attention, rarely related to methylphenidate.
Seizures in patients with no previous history	Withhold and discuss with specialist team.
Increase in seizure activity in patients with previous history of seizures	Discuss with specialist team immediately.
Suspected cerebral vasculitis (severe headache, numbness, weakness, paralysis, impairment of co-ordination, vision, speech, language or memory)	Stop methylphenidate and seek immediate medical attention, rarely related to methylphenidate.
Suspected medication misuse and diversion	Discuss with specialist team.

For a full list of Side Effects refer to the BNF or Summary of Product Characteristics (SPC)^{4,5,6,7}.

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

European guidelines on managing adverse effects of medication for ADHD were published in 2011. These provide additional guidance for clinicians.⁸

Relevant Contraindications

Methylphenidate is contraindicated in patients with severe depression; anorexia nervosa; psychosis; uncontrolled bipolar disorder; hyperthyroidism; cardiovascular disease (including heart failure, cardiomyopathy, severe hypertension, angina, myocardial infarction and arrhythmias); glaucoma; pheochromocytoma; vasculitis; cerebrovascular disorders

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Relevant Precautions

Particular caution is needed in the treatment of patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate.

Methylphenidate should be used with caution in the presence of tics or Tourette's syndrome, epilepsy and in patients with known drug or alcohol dependency because of a potential for abuse, misuse or diversion.

Concerta[®] XL, Ritalin[®] and Delmosart[®] are non-deformable formulations and 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.^{4,5,6}

Pregnancy and Breast-Feeding^{2,4,5,6,7,8}

There is limited experience of methylphenidate in 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.

If appropriate, female patients should be advised to use effective contraception during treatment with methylphenidate. In the event of a female patient becoming pregnant whilst taking methylphenidate, or wishing to start a family she should be advised to contact the specialist as soon as possible.

Methylphenidate should be avoided in breast-feeding (limited information available).

Clinically Relevant Medicine Interactions and their Management^{2,4,5,6,7,8}

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

- Monoamine Oxidase Inhibitors (MAOIs) including isocarboxazid, moclobemide, phenelzine and tranylcypromine - methylphenidate should not be used in combination with MAOIs or within 2 weeks of stopping a MAOI due to risk of hypertensive crisis.
- Linezolid – avoid concomitant use due to risk of hypertensive crisis.
- Selegiline/Rasagiline – avoid concomitant use due to risk of hypertensive crisis.
- Paliperidone/risperidone – caution with concomitant use, increased risk of dyskinesias.
- Methylphenidate may decrease the effectiveness of antihypertensives.
- Methylphenidate may inhibit the metabolism of coumarin anticoagulants such as warfarin (i.e. enhance the anticoagulant effect). Increased frequency of INR monitoring may be required.
- Methylphenidate may inhibit the metabolism of some anticonvulsants (phenytoin, phenobarbital, primidone).
- Methylphenidate may inhibit the metabolism of some antidepressants (SSRIs and TCAs).
- A small number of serious adverse events have been reported in patients receiving a combination of clonidine and methylphenidate although causality is not established.
- There is a risk of sudden blood pressure increase during surgery. If surgery is planned, methylphenidate treatment should not be used on the day of surgery.
- Medikinet XL 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 substance⁸.

For a full list of contraindications, precautions and medication interactions refer to the SPC.

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Information Given to Patient and Carers

- The specialist will provide relevant, age-appropriate written information to people with ADHD and their families and carers about diagnosis, assessment, support groups, self-help, psychological treatment, medication treatment and possible side-effects.
- An information leaflet for parents and carers is available from [Medicines for Children](#).

Patient / Carer Roles and Responsibilities

- The patient / carer will report any suspected adverse reactions to the GP for assessment
- The patient / carer will report to their GP or specialist any heart palpitations, tics, psychotic symptoms or onset or increase in seizures.
- The patient / carer will attend all follow-up appointments with GP and specialist. If they are unable to attend any appointments they should inform the relevant practitioner as soon as possible and arrange an alternative appointment.

Pharmacist Roles and Responsibilities

- Pharmacists are well placed to stress the value of a balanced diet, good nutrition and regular exercise for all patients with ADHD.
- Pharmacists can offer support to help improve treatment adherence in people with ADHD.
- Pharmacists are also well placed to keep any eye out for signs of possible drug misuse and diversion and inform the GP or specialist team of any concerns.
- Pharmacists can point out that in the cases of Concerta® XL & Delmosart® formulations the tablet membrane may pass through the gastrointestinal tract undamaged.⁵

References

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Version Control - Children and Young people ADHD - Methylphenidate Information Sheet			
Version	Author(s)	Date	Changes
1.1	Hannah Godden, Mental Health Interface and Efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCGs/ Nottinghamshire Healthcare NHS Foundation Trust	April 2021 (interim update)	<ul style="list-style-type: none"> -Added standard header & version control -Added link to Notts APC guideline on blood pressure and heart rate monitoring in children -Removed link to NUH guideline on blood pressure monitoring in children -Updated information about transition of care and Notts APC adult ADHD shared care protocol -Updated wording of pregnancy&breastfeeding and interactions sections in line with adult information sheet
1.0	<p>Professor Chris Hollis, Dr Barbara Houghton, Dr Val Yeung, John Lawton, Nottinghamshire Healthcare NHS Foundation Trust</p> <p>Dr Katherine Martin, Dr Amy Taylor, Dr Jane Williams, Dr Rosemary Gradwell (Community Paediatrics), Nottingham University Hospitals</p> <p>Dr Esther Corker, Dr Mike Farrall (Community Paediatrics), Sherwood Forest Hospitals</p> <p>Nick Sherwood, Mental Health Interface and Efficiencies Pharmacist, Nottinghamshire CCGs/ Nottinghamshire Healthcare NHS Foundation Trust</p>	December 2019	