INTENDED FOR UK HEALTHCARE PROFESSIONALS

Prescribing information and adverse event reporting is available by clicking this link.

Methylphenidate Hydrochloride

2mg/ml Oral Solution | Sugar Free

PRODUCT INFORMATION PACK

Pip code – 127-0784 EAN – 5391512458256

Methylphenidate Hydrochloride 2mg/ml oral solution is indicated as a 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.

The aim of this product information pack is to provide healthcare professionals with the information they require for activities such as completion of a formulary request for Methylphenidate Hydrochloride 2mg/ml oral solution for its licensed indication.

Consilient Health

UK-MPH-2(2) | September 2025

Methylphenidate Hydrochloride

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Consilient Health

INTRODUCTION

The information pack has been developed to provide a central resource that may be used for activities such as completion of a formulary request. The systems and processes required for formulary development are detailed in the NICE Medicines Practice Guideline 'Developing and updating local formularies'[1]. Healthcare professionals should submit applications to consider a new medicine for inclusion in the formulary; manufacturers may support evidence gathering.

The following should be included:

- Details of the healthcare professional making the application, including a declaration of interests
- Local patient population
- Details of the medicine, including strength, formulation, therapeutic drug class, indication, monitoring requirements and cost
- Evidence submission, with relevant supporting literature, covering efficacy, safety and cost effectiveness
- Comparison with existing treatments
- Likely place in therapy
- Recommendation for the decommissioning of a current formulary medicine, if applicable
- Resource impact

BACKGROUND

Attention deficit hyperactivity disorder

- Attention deficit hyperactivity disorder (ADHD) is defined as a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development.[2]
- The definition of ADHD requires that symptoms: start before 12 years of age; occur in two or more settings, such as at home and school; have been present for at least 6 months; interfere with or reduce the quality of social, academic or occupational functioning; do not occur exclusively during the course of a psychotic disorder and are not better explained by another mental disorder.[2]
- The cause of ADHD is unknown, but an interplay of multiple genetic and environmental factors that are thought to lead to altered brain neurochemistry and structure.[3]
- The global prevalence of ADHD in children is estimated to be around 5%, increasing to between 8% and 10% in studies based on US populations (where rates of diagnosis and treatment tend to be highest).[4]
- ADHD is more commonly diagnosed in boys than girls (prevalence ratios are generally estimated at 2–5:1, while clinic populations show a ratio as high as 10:1)[4]
- The greater prevalence of ADHD in boys may be because they are more likely to present with disruptive behaviour that prompts a referral, whereas girls more commonly have the inattentive subtype.[4]
- ADHD is associated with a range of psychiatric or neurodevelopmental comorbidity, including oppositional defiant disorder (ODD), conduct disorder, substance use disorder, and possibly mood disorders (e.g. depression and mania).[5]
- Autism spectrum disorder, dyslexia, dyscalculia and dyspraxia are over-represented in the ADHD patient population.[5]
- It is estimated that 20-60% of people affected by ADHD also present with learning disorders.[6]

BACKGROUND

Treatment of ADHD

- NICE guideline NG87 states that people with ADHD should have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.[7]
- When pharmacotherapy is considered appropriate, NICE guideline NG87 recommends offering methylphenidate (either short or long acting) as the first-line treatment for children aged 5 years and over and young people with ADHD.[7]
- All medication for ADHD should only be initiated by a healthcare professional with training and expertise in diagnosing and managing the condition.[7]
- While ADHD stimulants are proven to be effective, adherence is poor across all patient age groups.[8]
- Difficulty swallowing or an aversion to tablets may be a barrier to ADHD treatment.[8]
- People with learning difficulties are more likely to have dysphagia than others, which can make taking solid dose formulations more difficult than usual.[9]
- Paediatric patients are more likely to encounter difficulties swallowing solid dosage forms than adults.[8]
- Despite evidence of efficacy, many children who try stimulant medications for ADHD stop taking them, with reported rates of adherence varying from 25% to 50% twelve months after starting treatment.[10]
- Solid oral formulations may negatively affect adherence to ADHD therapy because of dosing inconvenience, patient discomfort or difficulty swallowing; efforts to refine stimulant formulations can potentially enhance adherence.[8]
- Clinicians should consider both medication class and formulation when seeking to optimise in outcomes in patients with ADHD.[8]
- Clinicians initiating medication for ADHD should ensure that treatment is tailored to the individual needs of the child, young person or adult (NICE NG87).[7]
- Titrate the dose against symptoms and adverse effects in line with the British National Formulary (BNF) or BNF for Children until dose optimisation is achieved; that is, reduced symptoms, positive behaviour change, improvements in education, employment and relationships, with tolerable adverse effects (NICE NG87).[7]
- Ensure that dose titration is slower and monitoring more frequent if any of the following are present in people with ADHD (NICE NG87):[7]
  - Neurodevelopmental disorders (e.g., autism spectrum disorder, tic disorders, learning disability [intellectual disability]).
  - Mental health conditions (e.g., anxiety disorders [including obsessive-compulsive disorder], schizophrenia or bipolar disorder, depression, personality disorder, eating disorder, post-traumatic stress disorder, substance misuse).
  - Physical health conditions (for example, cardiac disease, epilepsy or acquired brain injury).

EXPANDING TREATMENT OPTIONS

Mechanism of action	Methylphenidate is a mild central nervous system (CNS) stimulant with more prominent effects on mental than on motor activities. Its mode of action in man is not completely understood, but its effects are thought to be due to an inhibition of dopamine reuptake in the striatum, without triggering the release of dopamine. The mechanism by which methylphenidate exerts its mental and behavioural effects in children is not clearly established, nor is there conclusive evidence showing how these effects relate to the condition of the central nervous system. Methylphenidate is a racemic mixture containing d- and l-enantiomers, where the denantiomer is considered as the pharmacologically active enantiome.
Expanding treatment options	Methylphenidate Hydrochloride 2mg/ml oral solution has low viscosity[11] and is the only licensed liquid formulation of this medicine available for treatment of ADHD in children (aged 6 years and over when remedial measures alone prove insufficient). Methylphenidate Hydrochloride 2mg/ml oral solution has been developed to address the problem that, despite evidence of efficacy, children's adherence to stimulant medications is poor – and difficulty swallowing or an aversion to tablets can be a barrier to treatment.[8] Many children who try stimulant medications for ADHD stop taking them, with adherence rates varying from 25% to 50% twelve months after starting treatment.[10] The ability to offer Methylphenidate Hydrochloride 2mg/ml oral solution expands treatment options for children with ADHD, who may have swallowing difficulties, an aversion to tablets or a preference for non-solid formations. Prescribers will already be familiar with the efficacy and safety profile of Methylphenidate Hydrochloride 2mg/ml oral solution, as it is bioequivalent to Ritalin (Methylphenidate Hydrochloride) 10mg tablets.[12]
Medicine details	Methylphenidate Hydrochloride 2mg/ml oral solution
Marketing Company	Consilient Health Ltd.

SAFETY[13]

Pharmacology/ BNF class	Pharmacotherapeutic group: psychostimulants ATC code: NO6B AO4
Licensed indication	Methylphenidate is indicated as a 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.
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.
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. Patients should be monitored for the risk of diversion, misuse and abuse of methylphenidate.
Dosage and administration	Treatment must be initiated under the supervision of a specialist in childhood and/ or adolescent behavioural disorders. Careful dose titration is necessary at the start of treatment with methylphenidate. Dose titration should be started at the lowest possible dose. The maximum daily dose is 60mg. Children: (over 6 years). Begin with 5mg once or twice daily (e.g. at breakfast and lunch), increasing the dose and frequency of administration if necessary by weekly increments of 5-10mg in the daily dose. Doses above 60mg daily are not recommended. The total daily dose should be administered in divided doses. If the effect of the drug wears off too early in the evening, disturbed behaviour and/or inability to go to sleep may recur. A small evening dose may help to solve this problem. Methylphenidate treatment should not and need not, be indefinite. Methylphenidate treatment is usually discontinued during or after puberty. The oral solution should be swallowed with a drink of water.

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Contrain-dications	• Known sensitivity to methylphenidate or to any of the excipients in medicine. • Glaucoma • Phaechromocytoma • During treatment with monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days of discontinuing those drugs, due to 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, psycho-pathic/borderline personalitydisorder. Diagnosis or history of severe and episodic (Type 1) 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 or known risk factors for cerebrovascular disorders.
Special warnings and precautions	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.[13] Methylphenidate treatment is usually discontinued during or after puberty.[13] Patients on long-term therapy (i.e. over 12 months) must have careful ongoing monitoring for cardiovascular status, growth, appetite, development of *de novo* or worsening of pre-existing psychiatric disorders.[13] 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.[13]

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Special warnings and precautions	INDICATIONS AND PATIENT SELECTION Methylphenidate is not for all children with ADHD. Treatment decisions should consider symptom severity and chronicity. Long-term use (over 12 months) lacks sufficient controlled trial data and requires periodic reassessment, especially during puberty. Discontinuation during school holidays is recommended to evaluate the child's progress without medication. USAGE IN SPECIFIC AGE GROUPS Adults: Not approved for adult ADHD treatment; safety and efficacy are unconfirmed. Elderly: Not recommended; safety and efficacy data are lacking. Children under 6: Should not be used due to a lack of safety and efficacy data. CARDIOVASCULAR CONSIDERATIONS A detailed cardiac history and assessment are mandatory, especially for those with personal or family history of heart issues. Patients should be monitored for blood pressure and pulse changes at each dose adjustment and every six months thereafter. Methylphenidate is contraindicated for individuals with specific cardiovascular conditions Please refer to the Contraindications section for further information. For Cerebrovascular disorders, please refer to the Summary of Product Characteristics and the Contraindications section. PSYCHIATRIC PRECAUTIONS Psychiatric disorders are common in ADHD and may worsen with methylphenidate. Development or worsening or psychiatric disorders should be monitored at every dose adjustment, then at least every 6 months, and at every visit: discontinuation of treatment may be appropriate. Patients should be closely monitored for: Psychosis or mania: Can worsen; discontinuation may be necessary. Aggression and hostility: May emerge or worsen; regular monitoring advised. Suicidal ideation: Any emergence should prompt immediate evaluation. Tics and Tourette's syndrome: May worsen; family history should be evaluated. Anxiety, agitation, and bipolar disorder: Can worsen; detailed psychiatric history is required.

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Special warnings and precautions	OTHER RISKS Growth and Weight: Growth retardation has been reported. Monitor height, weight, and appetite every six months. Seizures: Caution in epilepsy patients; discontinue if seizure frequency increases. Abuse Potential: Methylphenidate has a risk of misuse and dependency. Monitor especially those with past substance abuse or co-morbid behavioural disorders. Withdrawal: May reveal underlying depression or chronic hyperactivity; careful supervision is advised. Fatigue: Should not be used for general fatigue prevention or in cases with a risk of misuse. Please refer to the Special Warnings and Precautions for use (section 4.4) of the Summary of Product Characteristics for full information.
Excipients with known effects	Sorbitol: This medicine contains 175mg sorbitol in each ml. The additive effect of concomitantly administered products containing sorbitol (or fruc-tose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use adminis-tered concomitantly. This medicine may also cause gastrointestinal discomfort and mild laxative effect. Patients with hereditary fructose intolerance (HFI) should not take this medicinal product. Propylene glycol: This medicine contains 90mg propylene glycol in each ml. Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction. While propylene glycol has not been shown to cause reproductive or de-velopmental toxicity in animals or human, it may reach the foetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on case by case basis.

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Excipients with known effects	Sodium benzoate: This medicine contains 1mg sodium benzoate in each ml. Sodium: This medicine contains less than 1mmol sodium (23mg) per ml, that is to say essentially 'sodium free'.
Interactions	ANTI-HYPERTENSIVE DRUGS Methylphenidate may decrease the effectiveness of drugs used to treat hypertension. USE WITH DRUGS THAT ELEVATE BLOOD PRESSURE Caution is advised in patients being treated with methylphenidate with other drugs that can also elevate blood pressure. Because of possible hypertensive crisis, methylphenidate is contraindicated in patients being treated (currently or within the preceding 2 weeks) with MAO inhibitors. USE WITH ALCOHOL Alcohol may exacerbate the adverse CNS effects of psychoactive drugs, including methylphenidate. It is therefore advisable for patients to abstain from alcohol during treatment. USE WITH ANAESTHETICS There is a risk of sudden blood pressure and heart rate increase during surgery. If surgery is planned, methylphenidate treatment should not be used on the day of surgery. USE WITH CENTRALLY-ACTING ALPHA-2 AGONISTS (e.g. clonidine) The long term safety of using methylphenidate in combination with clonidine or other centrally acting alpha-2 agonists has not been systematically evaluated. USE WITH DOPAMINERGIC DRUGS Caution is recommended when administering methylphenidate with dopaminergic drugs, including antipsychotics. Because a predominant action of methylphenidate is to increase extra cellular dopamine levels, methylphenidate may be associated with pharmacodynamic interactions when co-administered with direct and indirect dopamine agonists (including DOPA and tricyclic antidepressants) or with dopamine antagonists including antipsychotics.

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Fertility, pregnancy and lactation	PREGNANCY Data from a cohort study of in total approximately 3,400 pregnancies ex-posed in the first trimester do not suggest an increased risk of overall birth defects. There was a small increased occurrence of cardiac malformations (pooled adjusted relative risk, 1.3; 95 % CI, 1.0-1.6) corresponding to 3 additional infants born with congen-ital cardiac malformations for every 1000 women who receive methylphenidate during the first trimester of pregnancy, compared with non-exposed pregnancies. Cases of neonatal cardiorespiratory toxicity, specifically foetal tachycardia and respiratory distress have been reported in spontaneous reports. Studies in animals have only shown evidence of reproductive toxicity at maternally toxic doses. (See Section 5.3, Preclinical Safety Data). 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. BREAST-FEEDING Methylphenidate has been found in breast-milk of a women treated with methylphenidate. There is one case report of an infant who experienced an unspecified decrease in weight during the period of exposure but recovered and gained weight after the mother discontinued treatment with Methylphenidate. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from methylphenidate therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. FERTILITY No human data on the effect of methylphenidate on fertility are available.
Undesirable effects	The following information is taken from the Methylphenidate Hydrochloride 2 mg/ml Oral Solution Summary of Product Characteristics and shows all adverse drug reactions (ADRs) observed during clinical trials and post market spontaneous reports with methylphenidate – and those which have been reported with other methylphenidate hydrochloride formulations.[13]

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Undesirable effects	If ADRs with methylphenidate and the methylphenidate formulation frequencies were different, the highest frequency of both databases was used. Frequency estimate: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (< 1/10,000); not known (cannot be estimated from available data). INFECTIONS AND INFESTATIONS *Common*: Nasopharyngitis BLOOD AND LYMPHATIC DISORDERS *Very rare*: Anaemia, leucopenia, thrombocytopenia, thrombocytopenic purpura *Not known*: Pancytopenia IMMUNE SYSTEM DISORDERS *Uncommon*: Hypersensitivity reactions such as angioneurotic oedema, ana-phylactic reactions, auricular swelling, bullous conditions, exfoliative conditions, urticaria, pruritis, rashes and eruptions. METABOLISM AND NUTRITIONAL DISORDERS* *Common*: Anorexia, decreased appetite, moderately reduced weight and height gain during prolonged use in children. PSYCHIATRIC DISORDERS* *Very common*: Insomnia, nervousness *Common*: Anorexia, affect lability, aggression*, agitation*, anxiety*, depression*, irritability, abnormal behaviour, bruxism. *Uncommon*: Psychotic disorders*, auditory, visual, and tactile hallucinations*, anger, suicidal ideation*, mood altered, mood swings, restlessness, tearfulness, tics*, worsening of pre-existing tics or Tourette's syndrome*, hypervigilance, sleep disorder *Rare*: Mania*, disorientation, libido disorder *Very rare*: Suicidal attempt (including completed suicide)*, transient depressed mood*, abnormal thinking, apathy, repetitive behaviours, over-focusing *Not known*: Delusions*, thought disturbances*, confusional state, dependence, logorrhea. Cases of abuse and dependence have been described, more often with immediate release formulations (frequency not known)

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Undesirable effects	NERVOUS SYSTEM DISORDERS: *Very common:* Headache *Common:* Dizziness, dyskinesia, psychomotor hyperactivity, somnolence *Uncommon:* Sedation, tremor *Very rare:* Convulsions, choreo-athetoid movements, reversible ischaemic neurological deficit,neuroleptic malignant syndrome (NMS: Reports were poorly documented and, in most cases, patients were also receiving other drugs, so the role of methylphenidate is unclear). *Not known:* Cerebrovascular disorders* (including vasculitis, cerebral haemorrhages, cerebrovascular accidents, cerebral arteritis, cerebral occlusion), grand mal convulsions*, migraine, dysphemia. EYE DISORDERS *Uncommon:* Diplopia, blurred vision *Rare:* Difficulties in visual accommodation, mydriasis, visual disturbance CARDIAC DISORDERS* *Common:* Arrhythmia, tachycardia palpitations *Uncommon:* Chest pain *Rare:* Angina pectoris *Very rare:* Cardiac arrest, myocardial infarction *Not known:* Supraventricular tachycardia, bradycardia, ventricular extrasystoles, extrasystoles VASCULAR DISORDERS* *Common:* Hypertension *Very rare:* Cerebral arteritis and/or occlusion, peripheral coldness, Raynaud's phenomenon Respiratory, thoracic and mediastinal disorders *Common:* Cough, pharyngolaryngeal pain *Uncommon:* Dyspnoea *Not known:* Epistaxis GASTRO-INTESTINAL DISORDERS: *Common:* Abdominal pain, diarrhoea, nausea, stomach discomfort and vomiting. These usually occur at the beginning of treatment and may be alleviated by concomitant food intake. Dry mouth. *Uncommon:* Constipation

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Undesirable effects	HEPATOBILIARY DISORDERS *Uncommon:* Hepatic enzyme elevations *Very rare:* Abnormal liver functions, including hepatic coma SKIN AND SUBCUTANEOUS TISSUE DISORDERS *Common:* Alopecia, pruritis, rash, urticaria *Uncommon:* Angioneurotic oedema, bullous conditions, exfoliate conditions *Rare:* Hyperhidrosis, macular rash, erythema *Very rare:* Erythema multiforme, exfoliate dermatitis, fixed drug eruption MUSCULOSKELETAL, CONNECTIVE TISSUE AND BONE DISORDERS *Common:* Arthralgia *Uncommon:* Myalgia, muscle twitching, *Very rare:* Muscle cramps *Not known:* Trismus ** RENAL AND URINARY DISORDERS *Uncommon:* Haematuria *Not known:* Incontinence, Reproductive system and breast disorders *Rare:* Gynaecomastia *Not known:* Erectile dysfunction, priapism, erection increased and prolonged erection GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS *Common:* Pyrexia, growth retardation during prolonged use in children* *Uncommon:* Chest pain, fatigue *Very rare:* Sudden cardiac death* *Not known:* Chest discomfort, hyperpyrexia INVESTIGATIONS *Common:* Changes in blood pressure and heart rate (usually an increase) *, weight decreased* *Uncommon:* Cardiac murmur*, hepatic enzyme increased *Very rare:* Blood alkaline phosphatase increased, blood bilirubin increased, platelet countdecreased, white blood count abnormal * See section 4.4 "Special warnings and precautions for use" of the Summary of Product Characteristics. ** Based on the frequency calculated in adult ADHD studies (no cases were reported in the paediatric studies)
Shelf life	Unopened: 18 months after opening: 30 days

PLACE IN THERAPY

It is anticipated that Methylphenidate Hydrochloride 2mg/ml oral solution will be used 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, as stated in its licensed indication.[13] Methylphenidate Hydrochloride 2mg/ml oral solution has bioequivalence to Ritalin (Methylphenidate Hydrochloride) 10mg tablets,[12] so prescribers will already be familiar with its efficacy and safety profile.

Methylphenidate Hydrochloride 2mg/ml oral solution was developed to have a child-friendly neutral to sweet taste.[14] As the sorbitol component of the formulation provides adequate sweetness, the product has no artificial flavouring agents or sweeteners. A palatability study in found that acceptance of this oral solution was high, with 97.22% of subjects responding that daily dosing would be easy to accept and no subjects replying that they would be unable to take this medicine every day.[14] While this study was conducted in adults, it is assumed that these results would be similar in children.

As Methylphenidate Hydrochloride 2mg/ml oral solution is the only licensed liquid MPH formulation, it has particular utility for children who have difficulty swallowing or an aversion to tablets, which can be a barrier to treatment.[8] However, it is also anticipated that Methylphenidate Hydrochloride 2mg/ml oral solution will have a place in therapy for children who simply prefer a liquid formulation to tablets, even though they have no strong aversion to the latter, as it is easier for them to take. Providing choice in this regard is consistent with NICE guideline NG87 (Attention deficit hyperactivity disorder: diagnosis and management), which states that:[7]

"Before starting any treatment for ADHD, discuss the following with the person, and their family or carers as appropriate, encouraging children and young people to give their own account of how they feel: the importance of adherence to treatment and any factors that may affect this."

"Healthcare professionals initiating medication for ADHD should: ensure that treatment is tailored effectively to the individual needs of the child, young person or adult."

It is further anticipated that Methylphenidate Hydrochloride 2mg/ml oral solution will play a role in the care of some children who are receiving an extended release MPH formulation, but require an additional immediate release methylphenidate top-up to achieve desired efficacy. While they will still be taking an extended release methylphenidate formulation, the ability to top-up with Methylphenidate Hydrochloride 2mg/ml oral solution will reduce their solid 'pill burden' versus topping-up with tablets. This has the potential to support long-term compliance, particularly in children who find taking tablets difficult or simply prefer liquid formulations.

PLACE IN THERAPY

Where would prescribing of Methylphenidate Hydrochloride 2mg/ml oral solution take place?

Methylphenidate Hydrochloride 2mg/ml oral solution is expected to be prescribed as first-line pharmacotherapy in child psychiatric settings and paediatric practice. Treatment will be initiated in line with the licensed indication under the supervision of a specialist in childhood and/or adolescent behavioural disorders.

Will Methylphenidate Hydrochloride 2mg/ml oral solution replace any drugs already on the Formulary?

It is anticipated that Methylphenidate Hydrochloride 2mg/ml oral solution will be an additional formulation option that will reduce the use of methylphenidate tablets in children.

How does the cost of Methylphenidate Hydrochloride 2mg/ml oral solution compare with drugs already on the Formulary?

The NHS indicative price for a 150ml bottle of Methylphenidate Hydrochloride 2mg/ml oral solution is £85 (August 2025).

ON FORMULARY

Methylphenidate IR tablets already on formulary (August 2025)

Product	NHS indicative price for pack of 30 (£)
Medikinet 5mg tablets (Medice UK Ltd)	3.03
Methylphenidate 5mg tablets (AAH Pharmaceuticals Ltd)	7.80
Methylphenidate 5mg tablets (Kent Pharma [UK] Ltd)	4.55
Methylphenidate 5mg tablets (Viatris UK Healthcare Ltd)	2.58
Tranquilyn 5mg tablets (Genesis Pharmaceuticals Ltd)	3.03
Medikinet 10mg tablets (Medice UK Ltd)	5.49
Methylphenidate 10mg tablets (AAH Pharmaceuticals Ltd)	6.80
Methylphenidate 10mg tablets (Kent Pharma [UK] Ltd)	10.00
Methylphenidate 10mg tablets (Viatris UK Healthcare Ltd)	4.67
Ritalin 10mg tablets (InfectoPharm Arzneimittel und Consilium GmbH)	6.68
Tranquilyn 10mg tablets (Genesis Pharmaceuticals Ltd)	5.49
Medikinet 20mg tablets (Medice UK Ltd)	10.92
Methylphenidate 20mg tablets (AAH Pharmaceuticals Ltd)	13.00
Methylphenidate 20mg tablets (Kent Pharma [UK] Ltd)	16.38
Methylphenidate 20mg tablets (Viatris UK Healthcare Ltd)	9.28
Tranquilyn 20mg tablets (Genesis Pharmaceuticals Ltd)	10.92

IR: immediate release
All information is taken from bnf.nice.org.uk (Last accessed August 2025)

GUIDELINES AND RECOMMENDATIONS

NICE guideline NG87
(Attention deficit hyperactivity disorder: diagnosis and management) states that:[7]

- People with ADHD should have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.
- All medication for ADHD should only be initiated by a healthcare professional with training and expertise in diagnosing and managing the condition.
- When pharmacotherapy is considered appropriate, offer methylphenidate (either short or long acting) as the first-line treatment for children aged 5 years and over and young people with ADHD.
- Before starting any treatment for ADHD, discuss the importance of adherence to treatment and any factors that may affect this with the person and their family/carers, encouraging children and young people to give their own account of how they feel.
- Healthcare professionals initiating medication for ADHD should ensure that treatment is tailored effectively to the individual needs of the child, young person or adult.
- Titrate the dose against symptoms and adverse effects in line with the British National Formulary (BNF) or BNF for Children until dose optimisation is achieved; that is, reduced symptoms, positive behaviour change, improvements in education, employment and relationships, with tolerable adverse effects.
- Ensure that dose titration is slower and monitoring more frequent if any of the following are present in people with ADHD:
  - Neurodevelopmental disorders (e.g., autism spectrum disorder, tic disorders, learning disability [intellectual disability])
  - Mental health conditions (e.g., anxiety disorders [including obsessive–compulsive disorder], schizophrenia or bipolar disorder, depression, personality disorder, eating disorder, post-traumatic stress disorder, substance misuse)
  - Physical health conditions (for example, cardiac disease, epilepsy or acquired brain injury)

There may also be local guidelines and recommendations in addition to NICE guideline NG87, which should also be considered.

BIOEQUIVALENCE

Methylphenidate Hydrochloride 2mg/ml oral solution has been shown to bioequivalent to Ritalin (Methylphenidate Hydrochloride) tablets 10 mg by Novartis Pharmaceuticals UK.[12]

BIOEQUIVALENCE STUDY[12]

Design

A randomised, open-label, balanced, two treatment, two period, two sequence, single dose, crossover bioequivalence study compared Methylphenidate 2 mg/ml oral solution to Ritalin (Methylphenidate Hydrochloride) tablets 10 mg (distributed by Novartis Pharmaceuticals UK Ltd) in normal, healthy, adult, human subjects under fasting conditions.

The study was open-label in nature because blood concentration levels cannot be influenced by knowledge of the identity of the treatment. Use of a crossover design is appropriate since it enables comparison of treatments within the same study participant using intra-subject variability thus improving the precision of treatment comparisons. The 2 periods were separated by a washout period of 7 days, which is sufficient to ensure that blood concentrations are below the limit of quantitation at the start of the second period since the elimination half-life of methylphenidate after oral administration is approximately 2 hours.

A total of 36 subjects were planned and enrolled in the study. Out of which, one subject dropped out from period 2. Therefore, a total of 35 subjects completed all periods of the study. Pharmacokinetic analyses were performed on plasma concentration data of 36 subjects and data from 35 subjects who completed both periods of the study were considered for statistical analyses as per approved protocol. Plasma samples were analysed for methylphenidate hydrochloride using validated methodology.

BIOEQUIVALENCE

Results **Mean Pharmacokinetic Parameters of Methylphenidate (N=35)[12]**

Pharmacokinetic Parameters (Units)	Mean ± SD (%CV) (N=35)	
	Oral solution 2mg/ml	Tablets 10mg
Cmax (ng/mL)	8.72 ± 2.56 (29.39)	8.49 ± 2.36 (27.84)
AUC_{0-t} (hr*ng /mL)	42.24 ± 11.68 (27.66)	40.43 ± 10.93 (27.03)
AUC_{0-inf} (hr*ng /mL)	43.71 ± 11.85 (27.11)	41.84 ± 10.90 (26.06)
T_{max} (hr)	1.25 (0.75 – 2.67)	1.50 (0.75 – 2.67)
NK_{el}	7.63 ± 4.02 (52.64)	7.54 ± 2.98 (39.56)
K_{el} (hr^{-1})	0.21 ± 0.03 (15.41)	0.20 ± 0.03 (13.69)
K_{el} lower (hr)	4.44 ± 2.69 (60.65)	4.09 ± 2.11 (51.65)
K_{el} upper (hr)	17.49 ± 2.76 (15.78)	17.49 ± 2.58 (14.77)
$t_{½}$ (hr)	3.47 ± 0.60 (17.32)	3.46 ± 0.56 (16.24)
AUC Ratio (%)	96.49 ± 1.36 (1.41)	96.42 ± 1.35 (1.40)
Residual Area (%)	3.51 ± 1.36 (38.82)	3.58 ± 1.35 (37.83)

BIOEQUIVALENCE

Results Bioequivalence Assessment of Methylphenidate (N=35)[12]

PK Parameters (Unit)	Geometric Least Square Means†			ISCV %§	90% confidence interval limits‖
	Oral solution 2mg/ml	Tablets 10mg	(T/R) %‡		
LnC_{max} (ng/mL)	8.38	8.17	102.56	12.76	97.41% - 107.97%
LnAUC0-t (hr*ng /mL)	40.82	39.07	104.48	8.47	100.97% - 108.12%

†For loge-transformed results (Ln), value is the least-squares geometric mean
‡Ratio% of geometric least-squares means for loge-transformed results
§ISCV%= %Intra-subject coefficient of variation calculated from the mean square term of the ANOVA
‖Confidence interval on ratio

Rate of absorption (C_{max})

The 90% Confidence Interval of 97.41–107.97% was within the standard 90% CI of 80.00–125.00%. Based on these results, Methylphenidate 2 mg/ml Oral Solution is bioequivalent to Ritalin (Methylphenidate Hydrochloride) Tablets 10 mg by Novartis Pharmaceuticals UK Ltd with respect to the rate of absorption under fasting conditions.

Extent of absorption (AUC_{0-t})

The 90% Confidence Interval of 100.97–108.12% was within the standard 90% CI of 80.00–125.00%. Based on these results, Methylphenidate 2 mg/ml Oral Solution is bioequivalent to Ritalin (Methylphenidate Hydrochloride) Tablets 10 mg by Novartis Pharmaceuticals UK Ltd with respect to the extent of absorption under fasting conditions.

Safety assessment

Methylphenidate 2 mg/ml Oral Solution and Ritalin (Methylphenidate Hydrochloride) tablets 10 mg were generally well tolerated by all subjects. No adverse events was reported during the study.

Overall conclusions

Participants is this bioequivalence study demonstrated good tolerance to Methylphenidate Hydrochloride 2 mg/ml Oral Solution. Based on the pharmacokinetic data presented, it can be concluded that this formulation is bioequivalent to Ritalin (Methylphenidate Hydrochloride) Tablets 10 mg by Novartis Pharmaceuticals UK Ltd under fasting conditions.

FINANCIAL IMPLICATIONS AND SERVICE IMPACT

What is the cost per patient of the medicine each year?

Cost per patient per year will vary according to individual dosing needs. The NHS indicative price for a 150ml bottle of Methylphenidate Hydrochloride 2mg/ml oral solution is £85 (August 2025). Treatment is initiated with 5mg once or twice daily, carefully increased in weekly increments of 5-10mg in the daily dose as needed. Doses above 60mg daily are not recommended. See Section 4.2 of the Summary of Product Characteristics for full details of posology and administration.[13]

Is homecare available?

N/A

Estimated number of months of treatment per year

It is anticipated that Methylphenidate Hydrochloride 2mg/ml oral solution will be used for up to 12 months per year. Physicians electing 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 drug for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy.

FINANCIAL IMPLICATIONS AND SERVICE IMPACT

How will using this medicine affect how services are delivered to patients?

The use of Methylphenidate Hydrochloride 2mg/ml oral solution will not require any additional clinic visits others than those currently required for children receiving methylphenidate tablets for ADHD.

Are there any other non-medicine costs or savings related to using this medicine?

No

Equity of access

All patients with equal needs will have equal opportunities to access this medicine.

Methylphenidate Hydrochloride 2mg/ml oral solution is indicated for children with ADHD aged 6 years and over, as part of a comprehensive treatment programme when remedial measures alone prove insufficient.[13]

Methylphenidate Hydrochloride

2mg/ml Oral Solution | Sugar Free

- The **ONLY** licensed liquid formulation of Methylphenidate Hydrochloride
- Bioequivalent to Ritalin® (Methylphenidate Hydrochloride) 10mg tablets[12,13]
- Flexible dosing[12,13]
- Neutral to sweet taste, with no artificial flavouring agents or sweeteners[14]
- Low viscosity[11]

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