First licensed methylphenidate oral solution for children with ADHD aged 6 years and over[1]

INTENDED FOR UK HEALTHCARE PROFESSIONALS

CHOICE IS A PRETTY POWERFUL THING

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.[1] Treatment must be under the supervision of a specialist in childhood behavioural disorders.[1]

Prescribing information and adverse event reporting can be found on the last page.

ADHD: attention-deficit hyperactivity disorder.

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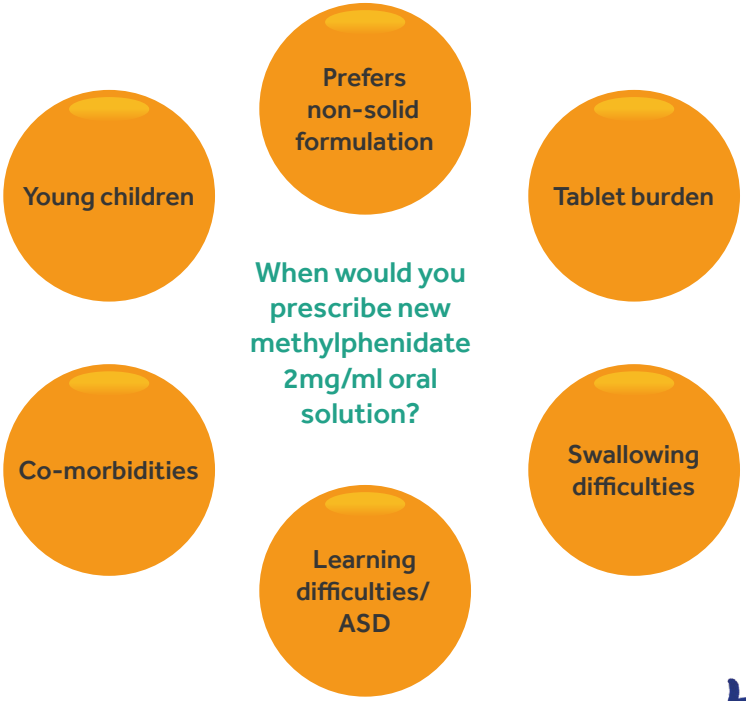
Consilient Health

Like all of us, children with ADHD appreciate having a choice, to help meet their individual needs and preferences. For example, while an oral solution of methylphenidate has particular utility for children who have difficulty swallowing or an aversion to tablets, others may simply prefer a non-solid formulation.

Providing a choice of formulation is consistent with NICE guideline NG87 (Attention deficit hyperactivity disorder: diagnosis and management), which says:[1] Before starting any treatment for ADHD, discuss the importance of adherence to treatment and any factors that may affect this, 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 or young person.

Can’t take, won’t take?



Methylphenidate Hydrochloride 2mg/ml oral solution expands formulation options for your paediatric patients aged 6 years and over, indicated as part of a comprehensive treatment programme when remedial measures alone prove insufficient:[1]

- The first and only liquid formulation of immediate release methylphenidate
- Bioequivalent to Ritalin® (methylphenidate hydrochloride) 10mg tablets[2]
- Enables child-friendly initiation of therapy or straightforward switching from a solid dose[2]
- Neutral to sweet taste, with no artificial flavouring agents or sweeteners[3]

Dosage[1]

- Careful dose titration is necessary at the start of treatment with methylphenidate. Dose titration should be started at the lowest possible dose
- Treatment should be initiated with a dose of 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
- The total daily dose should be given in divided doses
- Doses above 60mg daily are not recommended

Safety & Tolerability[1]

Methylphenidate commonly causes headache, insomnia, and nervousness (>1/10 occurrence). Monitoring is essential for children receiving the medication:

- **Growth:** Record height, weight, and appetite every 6 months using a growth chart.
- **Psychiatric health:** Monitor for new or worsening psychiatric disorders during dose adjustments and every 6 months.
- **Cardiovascular health:** Record blood pressure and pulse on a centile chart during dose adjustments and every 6 months.
- **Misuse risk:** Monitor for diversion, misuse, and abuse.

Refer to the Summary of Product Characteristics for a complete list of adverse effects, contraindications, and precautions.

Prescribe Methylphenidate Hydrochloride 2mg/ml oral solution for your paediatric patients aged 6 years+ who prefer a liquid formulation for treatment of ADHD

Useful information for parents and caregivers

- Methylphenidate should be stored safely and securely out of the reach of children[4,5] and in the packaging it comes in.[5] It must not be shared with anyone else.[4]
- Their child will be required to attend regular monitoring and review appointments with their healthcare professional throughout their treatment with methylphenidate[1,4,5]
- The parent/carer should check with their child's healthcare professional or pharmacist before giving any other medicines to their child, including herbal and complementary medicines.[5]

References

1. Methylphenidate Hydrochloride 2mg/ml oral solution Summary of Product Characteristics. Consilient Health Ltd.
2. Data on file, Module 2.5 – MPH OS bioequivalence to Ritalin 10mg tablets. Consilient Health Ltd – UK-MPH-83 June 2024.
3. Data on file, Methylphenidate Palatability Evaluation Assessment (10-2023), Consilient Health Ltd – UK-MPH-84 June 2024.
4. Methylphenidate Hydrochloride 2mg/ml oral solution Patient Information Leaflet. Consilient Health Ltd.
5. Medicines for Children - Methylphenidate for ADHD. Last updated July 2020. Available at: https://www.medicinesforchildren.org.uk/medicines/methylphenidate-for-adhd/. Accessed 02/12/24

Methylphenidate Hydrochloride 2mg/ml Oral Solution

PRESCRIBING INFORMATION

Methylphenidate Hydrochloride 2mg/mL oral Solution **(Methylphenidate hydrochloride).**
Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Indication Methylphenidate Hydrochloride 2mg/mL Oral Solution is indicated as part of a comprehensive treatment programme for Attention Deficit / Hyperactivity Disorder (ADHD) in children aged 6 years of age and over and adolescents when remedial measures alone prove insufficient. Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders. **Presentation** Methylphenidate Hydrochloride Oral Solution contains the active ingredient methylphenidate at 2mg/mL in solution. **Dosage and administration** Solution for oral use. Careful dose titration is necessary at the start of treatment with methylphenidate - 5mg once or twice daily increasing the dose and frequency of administration if required by weekly increments of 5-10mg in the daily dose. Doses above 60mg daily are not recommended. **Contraindications** Hypersensitivity to the active substance or to any of the inactive ingredients. Contraindicated in Glaucoma; phaeochromocytoma; during or within 14 days of discontinuing treatment with MAO; 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. Please refer to SmPC. **Warning and precautions** Patients on long term therapy (more than 12 months) require ongoing monitoring for cardiovascular status); for neurological signs and symptoms; for psychiatric/ neurological conditions; for growth. Methylphenidate should be de-challenged at least once yearly to assess the child's condition. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate. Potential for abuse, misuse or diversion in patients with known drug or alcohol dependency. Caution is advised in patients being treated with methylphenidate with any other active substances that can also elevate blood pressure. Alcohol may exacerbate the adverse CNS effect of psychoactive medicinal products, including methylphenidate. Caution is recommended when administering methylphenidate with dopaminergic substances. **Pregnancy and lactation** Not recommended. **Effects on ability to drive and use machines** Potentially hazardous activities such as driving or operating machinery should be avoided. **Undesirable effects** *(Very common)*: insomnia, nervousness and headache. *(Common)*: Naso-pharyngitis, upper respiratory tract infection, sinusitis, anorexia, decreased appetite, moderately reduced weight and height gain during prolonged use in children. Affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, mood swings, tics, initial insomnia, depressed mood, libido decreased, tension, bruxism, panic attack. Dizziness, dyskinesia, psycho-motor hyper-activity, somnolence, paraesthesia, tension headache, accommodation disorder, vertigo. Arrhythmia, tachy-cardia, palpitations, hyper-tension, cough, oro-pharyngeal pain, abdominal pain upper, diarrhoea, nausea, abdominal discomfort, vomiting, dry mouth, dyspepsia, alopecia, pruritis, rash, urticaria, arthralgia, muscle tightness, muscle spasms, erectile dysfunction, pyrexia, growth retardation during prolonged use in children. Fatigue, Irritability, feeling jittery, asthenia, thirst, changes in blood pressure and heart rate (usually an increase), weight decreased. *(Frequency not known)*: Pancytopenia disorders (including vasculitis, cerebral haemorrhages, cerebro-vascular accidents, cerebral occlusion), grand mal convulsion, migraine, dysphemia, mydriasis. Supra-ventricular tachycardia, bradycardia, ventricular extra-systoles, extra-systoles, trismus, incontinence, priapism, erection increased and prolonged erection, chest discomfort, hyperpyrexia. For uncommon, rare and very rare side effects please see SmPC for further information.

NHS Price £85 per 150ml bottle
Legal Category POM.MA **Number** PL 24837/0166
Market Authorisation Holder Consilient Health Ltd. Floor 3, Block 3, Miesian Plaza, Dublin 2, D02Y754, Ireland. September 2023
Job Code UK-MPH-4(1)a.
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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Consilient Health (UK) Ltd, No. 1 Church Road, Richmond upon Thames, Surrey TW9 2QE UK or drugsafety@consilienthealth.com