

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

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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