

## PRESCRIBING INFORMATION

**MEDIKINET® (methylphenidate hydrochloride) 5-20mg tablets.**

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

**Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MEDICE UK on 0204 582 2845, [pv-uk@medice.co.uk](mailto:pv-uk@medice.co.uk)**

Information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at <https://www.medicines.org.uk/emc/>.

**ACTIVE INGREDIENT:** Methylphenidate hydrochloride 5, 10 or 20mg.

**INDICATION:** Attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years and over as part of a comprehensive treatment programme when remedial measures alone prove insufficient. Treatment must be initiated under the supervision of a specialist in childhood behaviour disorders.

**DOSAGE and ADMINISTRATION:** Children 6 years and over: Conduct a baseline evaluation of patient's cardiovascular status, including blood pressure and heart rate, psychiatric and medical status and height and weight. 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. New patients: Careful dose titration is necessary at the start of treatment. Starting dose is 5mg once or twice daily, increasing, if necessary, by weekly increments of 5-10mg in the daily dose. Maximum daily dose is 60mg. The total daily dose should be administered in divided doses (usually 2-3). Administration: The tablets should be swallowed whole (or divided into halves) with the aid of liquid, either with or after meals. The last dose should not be given within 4 hours of bedtime. Long-term use (more than 12 months) in children and adolescents: Long term use has not been evaluated in controlled trials. Ongoing monitoring for cardiovascular status, growth, appetite, development of *de novo* or worsening of pre-existing psychiatric disorders is recommended. De-challenge at least once yearly to assess the child's condition. Adults: Medikinet is not licensed for use in adults. Use in the elderly: Not licensed. Children under 6 years: Not licensed. Caution should be exercised in patients with known hepatic and renal impairment.

**CONTRAINDICATIONS:** Known hypersensitivity to methylphenidate or excipients, glaucoma, phaeochromocytoma, during treatment with non-selective, irreversible monoamine oxidase inhibitors or discontinuation within 14 days, 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 and cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, channelopathies, pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including vasculitis or stroke.

**SPECIAL WARNINGS AND PRECAUTIONS:** Not recommended in patients with family history of sudden cardiac or unexplained death or malignant arrhythmia, known cardiac structural abnormalities, cardiomyopathy, serious heart rhythm abnormalities or other serious cardiac

problems. Caution with underlying medical conditions that might be compromised by increases in blood pressure or heart rate. Evaluate patients with emergent suicidal ideation or behaviour immediately. Monitor at every dose adjustment, then at least every 6 months: cardiovascular status, blood pressure and pulse, development or worsening of psychiatric disorders, worsening or emergence of psychotic or manic symptoms, worsening or emergence of aggressive or hostile behaviour, onset or exacerbation of tics, worsening of Tourette's syndrome, worsening of pre-existing anxiety, agitation or tension, particular care and dose monitoring in patients with comorbid bipolar disorder and patients with comorbid depressive symptoms at risk for bipolar. Record height, weight, and appetite on a growth chart. Assess neurological symptoms in patients at risk of cerebrovascular disorders. For abnormally sustained or frequent and painful erections seek immediate medical attention. Discontinue if seizure frequency increases or new onset seizures occur. Monitor for risk of abuse, misuse, and diversion. Caution with known drug or alcohol dependency. Supervise drug withdrawal. Not to be used for the prevention or treatment of normal fatigue states. This product contains lactose. Patients with galactose intolerance, lactase deficiency or glucose-galactose malabsorption should not take Medikinet. May induce false positive results for amfetamines during drug testing. In the event of adverse haematological effects, discontinuation of treatment should be considered. Use in renal or hepatic insufficiency: no experience.

**INTERACTIONS:** Coumarin anticoagulants, anticonvulsants (e.g., phenobarbital, phenytoin, primidone), tricyclic antidepressants and SSRIs, anti-hypertensives, drugs that elevate blood pressure, alcohol, halogenated anaesthetics, clonidine and other alpha-2 agonists, dopamine agonists or antagonists including antipsychotics. 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.

**PREGNANCY, LACTATION and FERTILITY:** Methylphenidate is not recommended in pregnancy and should not be used by breastfeeding mothers when the risk to the child outweighs the benefit of therapy to the mother. No data available on the effect of methylphenidate on fertility.

**DRIVING:** Caution is advised when driving, operating machines, or engaging in other potentially hazardous activities, as methylphenidate can cause dizziness, drowsiness and visual disturbances including difficulties with accommodation, diplopia, blurred vision, hallucinations and other CNS side effects.

**UNDESIRABLE EFFECTS: Very common:** Decreased appetite, insomnia, nervousness, headache, nausea and dry mouth. **Common:** Nasopharyngitis, anorexia, moderate reduction in weight and height gain during prolonged use in children, abnormal behaviour, aggression, affect lability, agitation, anxiety, depression, irritability, restlessness, sleep disorder, libido decrease, panic attack, stress, bruxism, tremor, somnolence, dizziness, dyskinesia, psychomotor hyperactivity, tachycardia, palpitations, arrhythmias, hypertension, peripheral coldness, cough, pharyngolaryngeal pain, dyspnoea, abdominal pain, stomach discomfort, vomiting, dyspepsia, toothache, diarrhoea, hyperhidrosis, alopecia, pruritus, rash, urticaria, arthralgia, pyrexia, growth retardation during prolonged use in children, feeling of inner restlessness, fatigue, thirst and changes in blood pressure and heart rate (usually an increase), weight decreased. **Other serious side effects:** leukopenia, thrombocytopenia, gastroenteritis, hypersensitivity reactions, psychotic disorders, mood swings, suicidal ideation/attempt/completion, neuroleptic malignant syndrome, cerebrovascular disorders, grand mal convulsions, angina pectoris, cardiac arrest, myocardial infarction, abnormal liver function including hepatic coma, priapism, sudden cardiac death. **Consult SmPC for all side effects.**

**PHARMACEUTICAL PRECAUTIONS:** Store below 25°C in original pack.

**LEGAL CATEGORY:** CD (Sch 2) POM.

<b>Product</b>	<b>NHS Cost (for 30 pack)</b>	<b>Marketing Authorisation Number:</b>
<b>Medikinet 5mg</b>	£3.03	PL 11243/0002
<b>Medikinet 10mg</b>	£5.49	PL 11243/0003
<b>Medikinet 20mg</b>	£10.92	PL 11243/0004

**MARKETING AUTHORISATION HOLDER:** MEDICE Arzneimittel Pütter GmbH & Co. KG.  
Kuhloweg 37, 58638 Iserlohn, Germany.

**Marketed in the UK** by MEDICE UK Ltd. Ground Floor, Unit B, The Chase, Foxholes Business Park, Hertford, Herts, SG13 7NN Tel: 020 4582 2845 Email: [medicalinformation@medice.co.uk](mailto:medicalinformation@medice.co.uk).

Medikinet is a registered trademark of MEDICE Arzneimittel Pütter GmbH & Co. KG.

**DATE OF REVISION OF PRESCRIBING INFORMATION:** July 2025