

## PRESCRIBING INFORMATION

**MEDIKINET® XL▼ (methylphenidate hydrochloride)** 5-60mg modified-release capsules, hard.  
Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. 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 020 4582 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, 20, 30, 40, 50 or 60mg.

**INDICATION:** Attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years and over and adults as part of a comprehensive treatment programme when remedial measures alone prove insufficient. Treatment must be initiated and supervised by a doctor specialised in the treatment of ADHD.

### **DOSAGE and ADMINISTRATION:**

Pre-treatment screening: If required by national practice, in adults new to Medikinet XL, cardiologist advice is needed prior to treatment initiation to check the absence of cardiovascular contraindications. Conduct a baseline evaluation of patient's cardiovascular status, including blood pressure and heart rate. A comprehensive history should document concomitant medications, past and present comorbid 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.

#### **Dose titration:**

Children: Careful dose titration is necessary at the start of treatment and should be started at the lowest possible dose. Starting dose is 5mg immediate-release methylphenidate once or twice daily. Medikinet XL 10mg once daily may be used in place of immediate-release methylphenidate 5mg twice daily from the beginning of treatment. Dose may be increased by 5-10mg according to tolerability and efficacy.

Children currently using methylphenidate: Children established on an immediate-release methylphenidate may be switched to the mg equivalent daily dose of Medikinet XL. Maximum daily dose in children is 60mg.

Continuation of therapy in adults: Adults who have shown clear benefit from treatment in childhood and/or adolescence may continue treatment with Medikinet XL into adulthood, initially at the same daily dose. Requirements for dose adjustment should be reviewed regularly.

Adults new to Medikinet XL: Careful dose titration is necessary at the start of treatment. Starting dose is 10mg daily increasing, if necessary, by weekly increments of 10mg in total daily dose. Total daily dose to be given in divided doses in the morning and at midday. Maximum daily dose in adults is 1mg/kg body weight to a maximum of 80mg daily.

#### **Administration:**

Children: Medikinet XL should be given in the morning with or after breakfast.

Adults: Medikinet XL should be given in the morning and at lunchtime with or after meals.

The capsules may be swallowed whole with liquids, or capsule contents sprinkled onto a small amount (tablespoon) of applesauce or yoghurt, taken immediately (not stored for future use) and followed by a drink. The capsule and contents must not be crushed or chewed.

**Caution is advised if long-acting formulations are used interchangeably due to differences between these formulations.**

**CONTRAINDICATIONS:** Known hypersensitivity to methylphenidate or excipients, glaucoma, pheochromocytoma, 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, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies, pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including vasculitis or stroke, history of pronounced acidity of the stomach with a pH due above 5.5, in therapy with H<sub>2</sub> receptor blockers, proton pump inhibitors or in antacid therapy.

**SPECIAL WARNINGS AND PRECAUTIONS:**

Long-term use (more than 12 months): Long-term use has not been systematically evaluated in controlled trials. Ongoing monitoring for cardiovascular status, growth (children), weight, appetite, development of *de novo* or worsening of pre-existing psychiatric disorders is recommended. De-challenge at least once yearly to assess patient's condition.

Use in patients >60 years: Not licensed.

Children under 6 years: Not licensed.

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. Sudden cardiac or unexplained death has been reported. Seek prompt specialist evaluation if symptoms suggestive of cardiac disease develop.

Caution with underlying medical conditions that might be compromised by increases in blood pressure or heart rate. Increases in systolic and diastolic blood pressure have been observed in clinical trials.

Methylphenidate should be discontinued in patients under treatment with repeated measures of tachycardia, arrhythmia or increased systolic blood pressure (>95th percentile) and consider referral to a cardiologist.

Assess neurological symptoms at every visit in patients at risk of cerebrovascular disorders. For abnormally sustained or frequent and painful erections seek immediate medical attention. Conduct a baseline assessment then monitor at every dose adjustment, then at least every 6 months and at every visit: 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 with comorbid bipolar disorder and patients with comorbid depressive symptoms at risk for bipolar.

Evaluate patients with emergent suicidal ideation or behaviour immediately. Record height, weight and appetite in children at least 6 monthly on a growth chart. Weight decrease has been reported in adults, so weight should be monitored regularly. Caution in patients with epilepsy: 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. May induce false positive results for amphetamines during drug testing.

Caution should be exercised in patients with known hepatic and renal impairment. In the event of adverse haematological effects, consider discontinuation of treatment.

Patients with fructose intolerance, glucose-galactose malabsorption, or sucrose isomaltose insufficiency should not take Medikinet XL.

**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 and H<sub>2</sub> receptor blockers, proton pump inhibitors and antacids. 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 machinery, or engaging in other potentially hazardous activities, as methylphenidate can cause dizziness, drowsiness, visual disturbances, including difficulties with accommodation, diplopia, blurred vision, hallucinations and other CNS side effects.

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

**PHARMACEUTICAL PRECAUTIONS:** Store below 30°C in original pack.

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

Product	NHS Cost (for 30 pack)	Marketing Authorisation Number
Medikinet XL 5mg	£24.04	PL 11243/0010
Medikinet XL 10mg	£24.04	PL 11243/0005
Medikinet XL 20mg	£28.86	PL 11243/0006
Medikinet XL 30mg	£33.66	PL 11243/0007
Medikinet XL 40mg	£57.72	PL 11243/0008

<b>Medikinet XL 50mg</b>	£62.52	PL 11243/0011
<b>Medikinet XL 60mg</b>	£67.32	PL 11243/0012

**MARKETING AUTHORISATION HOLDER:**

MEDICE Arzneimittel Pütter GmbH & Co. KG.  
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