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

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/. Adverse events should also be reported to Flynn Pharma Ltd. Medical Information: Tel 01438 727822.

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.

INDICATIONS: 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: 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 (children only) and weight on a growth chart.

Dose titration:
Children: Careful dose titration is necessary at the start of treatment. 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.
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. Requirement 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 of soft food, taken immediately and followed by a drink. The capsule and contents must not be crushed or chewed.

CONTRAINDICATIONS: Known sensitivity 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, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies, pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including vasculitis or stroke, history of pronounced anacidity of the stomach.

SPECIAL WARNINGS AND PRECAUTIONS:

Long-term use (more than 12 months): Long-term use has not been 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 recommended.

Children under 6 years: Not recommended.

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.

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 and dose monitoring in patients 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 (children), weight and appetite at least 6 monthly on a growth chart.

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 amfetamines during drug testing.

Use in renal or hepatic insufficiency: no experience.

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), tricyclics 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_2 receptor blockers and antacids.

PREGNANCY, LACTATION and FERTILITY: Methylphenidate is not recommended in pregnancy and should not be used by breast feeding 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.

UNDESIRABLE EFFECTS: **Very common:** Insomnia, nervousness, headache, palpitations. **Common:** Nasopharyngitis, anorexia, decreased appetite, reduced weight and height gain during prolonged use in children, affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, panic attack, stress, bruxism, dizziness, dyskinesia, psychomotor hyperactivity, somnolence, arrhythmia, tachycardia, hypertension, cough, pharyngolaryngeal pain, abdominal pain, diarrhoea, nausea, stomach discomfort and vomiting, dry mouth, dyspepsia, toothache, alopecia, pruritus, rash, urticaria, hyperhidrosis, arthralgia, pyrexia, changes in blood pressure and heart rate, weight decreased. **Other side-effects:** hypersensitivity reactions, psychotic disorders, suicidal ideation/ attempt/ completion, neuroleptic malignant syndrome, cerebrovascular disorders, cerebrovascular accidents, grand mal convulsions, angina pectoris, cardiac arrest, myocardial infarction, cardiac arrhythmias, abnormal liver function including hepatic coma, priapism, sudden cardiac death. **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	PL11243/0010
Medikinet XL 10mg	£24.04	PL11243/0005
Medikinet XL 20mg	£28.86	PL11243/0006
Medikinet XL 30mg	£33.66	PL11243/0007
Medikinet XL 40mg	£57.72	PL11243/0008
Medikinet XL 50mg	£62.52	PL11243/0011
Medikinet XL 60mg	£67.32	PL11243/0012

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

Marketed in the UK by Flynn Pharma Ltd, Hertlands House, Primett Road, Stevenage, Herts, SG1 3EE.
Tel: 01438 727822 Email: medinfo@flynnpharma.com
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