**PRESCRIBING INFORMATION**
Please refer to Summary of Product Characteristics (SmPC) before prescribing.

**MEDIKINET TABLETS 5-20mg.**

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

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

**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. Maximum daily dose is 60mg. **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 begiven 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 recommended. **Children under 6 years:** Not recommended.

**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 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 increase 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), 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.

**FERTILITY, PREGNANCY and LACTATION:** 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.

**DRIVING:** Caution is advised when driving, operating machines, or engaging in other potentially hazardous activities.

**UNDESIRABLE EFFECTS: Very common***:* Insomnia, nervousness, headache. **Common***:* Nasopharyngitis, anorexia, decreased appetite, moderately reduced weight and height gain during prolonged use, affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, panic attack*, stress*, bruxism*, dizziness, dyskinesia, psychomotor hyperactivity, somnolence, arrhythmia, tachycardia, palpitations, hypertension, cough, pharyngolaryngeal pain, abdominal pain, diarrhoea, nausea, stomach discomfortand vomiting, dry mouth, dyspepsia*, toothache*, alopecia, pruritus, rash, urticaria, arthralgia, pyrexia, growth retardation during prolonged use. Consult SmPC in relation to less common side effects. **Serious**: Sudden death.
*ADRs from clinical trials in adult patients that were not reported in children and adolescents.

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

**DATE OF LAST REVISION OF PI:** March 2021

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

| Product | NHS Cost (for 30 pack) | Marketing Authorisation Number: |
|---|---|---|
| **Medikinet 5mg** | £3.03 | PL11243/0002 |
| **Medikinet 10mg** | £5.49 | PL11243/0003 |
| **Medikinet 20mg** | £10.92 | PL11243/0004 |

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

**Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. 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 http://www.medicines.org.uk/emc/

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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