Affenid XL (methylphenidate hydrochloride) 18 mg, 27 mg, 36 mg and 54 mg prolonged release tablets Prescribing Information. Prescribers should consult the SmPC before prescribing.

Presentation: Each prolonged-release tablet contains 18mg, 27mg, 36mg or 54mg methylphenidate hydrochloride respectively.

Also contains 4mg, 3.4mg, 6.6mg and 6.8mg lactose monohydrate respectively.

Indications: Indicated as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over and adults when remedial measures alone prove insufficient.
Treatment must be initiated and supervised by a physician specialised in the treatment of ADHD. Please refer to the SmPC for full details.

Dosage and administration: *Pre-treatment screening:* In adults new to methylphenidate, cardiologist advice is needed prior to treatment initiation. Baseline cardiovascular evaluation is necessary. Document concomitant medications, past and present co-morbid medical and psychiatric disorders/symptoms, family history of sudden cardiac/unexplained death, height in children only and weight. *Ongoing monitoring:* Growth, psychiatric and cardiovascular status should be continuously monitored. Record blood pressure and pulse on a centile chart at each adjustment and then at least every 6 months. Height, weight and appetite in children should be recorded. Weight should be recorded for adults regularly. Development of de novo or worsening of pre-existing psychiatric disorders should be monitored. Monitor for the risk of diversion, misuse and abuse of methylphenidate. *Dose titration:* Careful dose titration is necessary. Start at the lowest dose. Dose adjustment may proceed at weekly intervals. Maximum dosage is 54mg in children and 72 mg in adults.

Patients new to methylphenidate: lower doses of short-acting methylphenidate may be sufficient. Careful dose titration is required. Recommended starting dose is 18mg once daily.
Patients currently using methylphenidate: Dosing recommendations are based on current dose regimen and clinical judgement.
Long-term use: No data. If used over 12 months, periodically re-evaluate the long-term usefulness with trial periods off medication to assess patient's functioning without pharmacotherapy. Recommended to de-challenge at least once yearly to assess patient's condition. *Dose reduction and discontinuation:* Stop treatment if the symptoms do not improve over a one-month period. See SmPC for instructions.

Method of Administration: oral use once daily in the morning. May be administered with or without food. Swallowed whole with the aid of liquids. Must not be chewed, divided or crushed.

Special Populations: *Paediatric Population*: not for use in patients aged under 6 years. *Elderly:* Should not be used. *Hepatic or renal impairment:* no data.

Fertility, pregnancy and lactation: *Pregnancy:* Not recommended. *Breastfeeding*: Decide whether to discontinue breastfeeding or methylphenidate therapy based on the benefit of breast feeding for the child versus the benefit of methylphenidate therapy for the woman. *Fertility:* No human data available. No relevant effects observed in the non-clinical studies.

Contraindications: Hypersensitivity to methylphenidate or any of the excipients, glaucoma, phaeochromocytoma, during treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within 14 days of discontinuing a MAO inhibitor, 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 bipolar disorder (that is not well-controlled), pre-existing cardiovascular disorders (including severe hypertension, heart failure, arterial occlusive disease, angina pectoris, 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.

Special warnings and precautions: *Cardiovascular status:* Patients should have a careful history and physical exam to assess for the presence of cardiac disease. During treatment, if patients develop any symptoms suggestive of cardiac disease, they should undergo specialist cardiac evaluation. Use with caution in patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate. Blood pressure and pulse should be recorded at each adjustment of dose and then at least every 6 months. Should be discontinued in patients under treatment with repeated measures of tachycardia, arrhythmia or increased systolic blood pressure (>95th percentile) and referral to a cardiologist should be considered. *Sudden death and pre-existing cardiac structural abnormalities or other serious cardiac disorders:* Sudden death has been reported in patients with the use of stimulants. Stimulants are not recommended in patients with known cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities or other serious cardiac problems. *Adults:* Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs. *Misuse and cardiovascular events:* Misuse of stimulants may be associated with sudden death and other serious cardiovascular events. *Cerebrovascular disorders:* Patients with risk factors should be assessed at every visit. *Psychiatric disorders:* Development or worsening should be monitored at every adjustment of dose, then at least every 6 months, and at every visit. May exacerbate symptoms of behavioral disturbance and thought disorder. Treatment-emergent psychotic

symptoms or mania can be caused. Emergence or worsening of aggressive or hostile behaviour can be caused with stimulants. Emergent suicidal ideation or behavior should be evaluated. Associated with onset or exacerbation of motor and verbal tics. Monitoring should be at every adjustment of dose and then at least every 6 months or every visit. Associated with worsening of pre-existing anxiety, agitation or tension. Should be monitored regularly. Take care in comorbid bipolar patients. Close monitoring is essential. *Growth:* height, weight and appetite should be recorded in children. Weight should be monitored in adults. *Seizures:* use with caution in patients with epilepsy. *Priapism*: prolonged and painful erections have been reported. *Use with serotonergic medicinal products*: Serotonin syndrome has been reported. Must be discontinued as soon as possible if serotonin syndrome is suspected. *Abuse, misuse and diversion:* carefully monitor for the risk of diversion, misuse and abuse. *Withdrawal:* careful supervision is required. *Fatigue:* Should not be used to prevent or treat normal fatigue. *Choice of methylphenidate formulation:* must be decided by the specialist. *Hematological effects:* Patients requiring long-term therapy should be monitored. *Drug screening:* May induce a false positive lab test for amphetamines. *Effects in case of misuse as doping agent:* can lead to positive results. *Contains lactose:* patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose -galactose malabsorption should not take this product. This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

Drug Interactions: Caution combining with other medicines, especially medicines with a narrow therapeutic window, coumarin anticoagulants, anticonvulsants some antidepressants, anti-hypertensive medicinal products, medicinal products that elevate blood pressure, alcohol, halogenated anaesthetics, centrally acting alpha-2 agonists, dopaminergic medicinal products.

Effects on ability to drive/use machines: Can cause dizziness, drowsiness and visual disturbances. May have a moderate influence. Patients should be warned of these possible effects. This medicine can impair cognitive function and can affect a patient's ability to drive safely.

Undesirable effects: Nasopharyngitis, upper respiratory tract infection, sinusitis, anaemia, leukopenia, thrombocytopenia, thrombocytopenic purpura, pancytopenia, hypersensitivity reactions such as angioneurotic oedema, anaphylactic reactions, auricular swelling, bullous conditions, exfoliative conditions, urticaria, pruritus, rashes and eruptions, anorexia, decreased appetite, moderately reduced weight and height gain during prolonged used in children, insomnia, nervousness, affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, mood swings, tics, initial insomnia, depressed mood, libido decreased, tension, bruxism, panic attack, psychiatric disorders, psychotic disorders, auditory, visual and tactile hallucinations, anger, suicidal ideation, worsening of pre-existing tics or Tourette's syndrome, mania, disorientation, confusional state, suicidal attempt, delusions, thought disturbances, abuse and dependence, headache, dizziness, dyskinesia, psychomotor hyperactivity, somnolence, paraesthesia, tension headache, convulsion, neuroleptic malignant syndrome (NMS) cerebrovascular disorders, accommodation disorder, diplopia, vertigo, arrhythmia, tachycardia , palpitations, chest pain, angina pectoris, cardiac arrest, myocardial infarction, supraventricular tachycardia, bradycardia, ventricular extrasystoles, extrasystoles , hypertension, cerebral arteritis and/or occlusion, peripheral coldness, Raynaud's phenomenon, cough, oropharyngeal pain, abdominal pain upper, diarrhoea, nausea, , abdominal discomfort, vomiting, dry mouth, dyspepsis, alanine aminotransferase increased, abnormal liver function including acute hepatic failure and hepatic coma, alopecia, pruritus, rash, urticaria, hyperhidrosis, erythema multiforme arthralgia, muscle tightened, muscle spasm, erectile dysfunction, priapism, pyrexia, growth retardation during prolonged use in children, fatigue, irritability, feeling jittery, asthenia, thirst, fatigue, thirst, sudden cardiac death, chest discomfort, hyperpyrexia, changes in blood pressure and heart rate, cardiac murmur, platelet count decreased, white blood count abnormal. See SmPC for full list of adverse events.

Pack size and UK list price:
Affenid XL 18mg tablets (PL 17780/1170), pack size: 30, £ 10.90
Affenid XL 27mg tablets (PL 17780/1171), pack size: 30, £ 12.87
Affenid XL 36mg tablets (PL 17780/1172), pack size: 30, £ 14.85
Affenid XL 54mg tablets (PL 17780/1173),pack size: 30, £ 25.75

Legal category: POM

Marketing Authorisation Holder: Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

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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 Zentiva via email to PV-United-Kingdom@zentiva.com or via phone on 0800 090 2408.