PRESCRIBING INFORMATION

Xenidate XL 18 mg prolonged-release tablets
Xenidate XL 27 mg prolonged-release tablets
Xenidate XL 36 mg prolonged-release tablets
Xenidate XL 54 mg prolonged-release tablets
(Methylphenidate hydrochloride)

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

Indication: Xenidate XL prolonged-release tablets are indicated as part of a comprehensive treatment programme for Attention Deficit / Hyperactivity Disorder (ADHD) in children aged 6 years of age and over and adolescents when remedial measures alone prove insufficient. Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders. It should always be used according to the licensed indication and according to prescribing / diagnostic guidelines.

Presentation: Xenidate XL prolonged-release tablets contain the active ingredient methylphenidate. 18 mg tablet contains 18mg methylphenidate hydrochloride (equivalent to 15.57 mg methylphenidate). 27mg contains 27 mg methylphenidate hydrochloride (equivalent to 23.35 mg methylphenidate). 36 mg contains 36 mg methylphenidate hydrochloride (equivalent to 31.13 mg methylphenidate) 54mg contains 54 mg methylphenidate hydrochloride (equivalent to 46.7 mg methylphenidate). Xenidate 27 mg, 36 mg & 54 mg tablets have a break line on both sides and can be divided into equal doses.

Dosage and administration: Tablet for oral use. Taken once daily in the morning with or without food. Dose titration: Necessary at the start of treatment with methylphenidate. Start at the lowest possible dose. The dosage may be adjusted in 18 mg increments. In general, dosage adjustment may proceed at approximately weekly intervals. The maximum daily dosage of methylphenidate is 54 mg. Patients new to methylphenidate: Lower doses of short-acting methylphenidate formulations may be considered sufficient to treat patients new to methylphenidate. The recommended starting dose of methylphenidate for patients who are not currently taking methylphenidate, or for patients who are on stimulants other than methylphenidate, is 18 mg once daily. Patients currently using methylphenidate: Recommended dose for patients who are currently taking methylphenidate three times daily at doses of 15 mg/day is 18 mg once daily, 30 mg/day is 36 mg once daily and 45 mg/day is 54 mg once daily. If improvement is not observed after appropriate dosage adjustment over a one-month period, the medicinal product should be discontinued.

Contraindications: Hypersensitivity to the active substance or to any of the inactive ingredients. Contraindicated in Glaucoma; phaeochromocytoma; during or within 14 days of discontinuing treatment with MAO; 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 (disorders caused by the dysfunction of ion channels). Pre-existing cerebrovascular disorders e.g., cerebral aneurysm, vascular abnormalities including vasculitis or stroke.

Warning and precautions: Patients on long term therapy (more than 12 months) require ongoing monitoring (at each dose adjustment and then at least every 6 months) for cardiovascular status (blood pressure and pulse); for neurological signs and symptoms (cerebrovascular disorders and additional risk factors); for psychiatric/ neurological conditions (including exacerbation of pre-existing psychotic or manic symptoms, emergence or worsening of aggressive/hostile behaviour, tics, anxiety, agitation or tension, suicidal ideation, possible precipitation of a mixed/ manic episode in patients with comorbid bipolar disorder, epilepsy (may lower convulsive threshold)); for growth (height, weight and appetite). Methylphenidate should be de-challenged at least once yearly to assess the child's condition (preferably during times of school holidays). Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate. Potential for abuse, misuse or diversion in patients with known drug or alcohol dependency. Not to be used for the prevention or treatment of normal fatigue states. No experience in patients with renal or hepatic insufficiency. If leukopenia, thrombocytopenia, anaemia or other alterations, including those indicative of serious renal or hepatic disorders present, discontinuation of treatment should be considered. Should not be given to patients with pre-existing severe GI narrowing (pathologic or iatrogenic) or in patients with dysphagia or significant difficulty in swallowing tablets. Prolonged and painful erections have been reported in association with methylphenidate products, mainly in associated with change in treatment regimen. If serotonin syndrome is suspected, treatment should be discontinued as soon as possible. Contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. Sudden death has been reported in association with the use of stimulants of the central nervous system at usual doses in children, some of whom had structural cardiac

abnormalities or other serious heart problems. This product contains methylphenidate which may induce a false positive laboratory test for amphetamines, particularly with immunoassay screen test.

Interaction with other medicinal products: Caution is recommended when combining with other medicinal products. Methylphenidate may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (e.g. phenobarbital, phenytoin, primidone) and some antidepressants (tricyclics and selective serotonin reuptake inhibitors). When starting or stopping treatment, it may be necessary to adjust the dosage and establish their plasma concentrations (or for coumarin, coagulation times). May decrease the effectiveness of medicinal products used to treat hypertension. Caution is advised in patients being treated with methylphenidate with any other active substances that can also elevate blood pressure. Alcohol may exacerbate the adverse CNS effect of psychoactive medicinal products, including methylphenidate. It is therefore advisable for patients to abstain from alcohol during treatment. Reports of serotonin syndrome following coadministration of methylphenidate with serotonergic medicinal products. If concomitant use of methylphenidate with a serotonergic medicinal product is warranted, prompt recognition of the symptoms of serotonin syndrome is important. Caution is recommended when administering methylphenidate with dopaminergic substances, including antipsychotics. There is a risk of sudden blood pressure increase during surgery. If surgery is planned, methylphenidate treatment should not be used on the day of surgery.

Pregnancy and lactation: Methylphenidate is not recommended for use during pregnancy. It is possible that methylphenidate is excreted in human breast milk.

Effects on ability to drive and use machines: Methylphenidate can cause dizziness, drowsiness and visual disturbances including difficulties with accommodation, diplopia and blurred vision. It may have a moderate influence on the ability to drive and use machines. Potentially hazardous activities such as driving or operating machinery should be avoided.

Undesirable effects: (*Very common):* insomnia, nervousness and headache. (*Common)*: Naso-pharyngitis, upper respiratory tract infection, sinusitis, anorexia, decreased appetite, moderately reduced weight and height gain during prolonged use in children. Affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, mood swings, tics, initial insomnia, depressed mood, libido decreased, tension, bruxism, panic attack. Dizziness, dyskinesia, psycho-motor hyper-activity, somnolence, paraesthesia, tension headache, accommodation disorder, vertigo. Arrhythmia, tachy-cardia, palpitations, hyper-tension, cough, oro-pharyngeal pain, abdominal pain upper, diarrhoea, nausea, abdominal discomfort, vomiting, dry mouth, dyspepsia, alopecia, pruritis, rash, urticaria, arthralgia, muscle tightness, muscle spasms, erectile dysfunction, pyrexia, growth retardation during prolonged use in children. Fatigue, Irritability, feeling jittery, asthenia, thirst, changes in blood pressure and heart rate (usually an increase), weight decreased. (*Frequency not known):* Pancytopenia disorders (including vasculitis, cerebral haemorrhages, cerebro-vascular accidents, cerebral occlusion), grand mal convulsion, migraine, dysphemia, mydriasis. Supra-ventricular tachycardia, bradycardia, ventricular extra-systoles, extra-systoles, trismus, incontinence, priapism, erection increased and prolonged erection, chest discomfort, hyperpyrexia. For uncommon, rare and very rare side effects please see SmPC for further information.

Legal Category: POM **Marketing Authorisation Number**: PL 04569/1417 (18mg), PL 04569/1605, (27mg), PL 04569/1418 (36mg), PL 04569/1419 (54mg) **MAH:** Generics [UK] Limited t/a Mylan, Station close, Potters Bar, Hertfordshire, EN6 1TL, UK**. NHS Price:** Xenidate 18mg £15.57, Xenidate 27mg £18.39, Xenidate 36mg £21.21 & Xenidate 54mg £36.79 **Date of Revision of Prescribing Information:** August 2022 **Veeva reference:** MET-2022-0034

The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm and from Mylan Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com

Please continue to report suspected adverse drug reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions online via the Yellow Card Scheme website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789. Adverse reactions/events should also be reported to MAH at e-mail address: pv.uk@viatris.com