Xenidate XL®

(Methylphenidate hydrochloride)

Xenidate XL® is 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 under the supervision of a specialist in childhood behavioural disorders.

Dear _____,

Please be aware that your patient, _____, is being switched from Concerta XL® (prolonged-release methylphenidate hydrochloride) to a generic version called Xenidate XL® (prolonged-release methylphenidate hydrochloride) for the treatment of ADHD.

Xenidate XL® provides similar bioequivalence to Concerta XL® in both efficacy and tolerability, and provides a similar biphasic release profile across a 24 hour period. The reason your patient is being switched is down to cost – Xenidate XL® provides similar ADHD symptom control at a 50% cost saving to the NHS versus Concerta XL®.[1-3]

Viatris has also developed a number of materials to help support your patients through their switch to Xenidate XL®, including dedicated Xenidate XL® websites for both you and your patients:

- Please refer your patients to **XenidateXL.co.uk/patient** for support and further information
- Please refer to **XenidateXL.co.uk/HCP** for healthcare professional-specific information
- Please also refer to Xenidate XL® prescribing information (see overleaf) and summary of product characteristics for more information

Signed

_____

References

1. Viatris data on file (myl_xen_dof_v1).
2. Xenidate XL®. Summary of Product Characteristics (SPC) – all doses. April 2022.
3. NICE. Methylphenidate hydrochloride. https://bnf.nice.org.uk/medicinal-forms methylphenidate-hydrochloride.html (last accessed April 2022).

Reporting of adverse reactions:

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 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/SystmOne/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.

Job number: MET-2022-0003 Date of preparation: August 2022

VIATRIS

XENIDATE XL (METHYLPHENIDATE HYDROCHLORIDE) 18mg, 27mg, 36mg, 54mg PROLONGED-RELEASE TABLETS
PRESCRIBING INFORMATION

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

Indication: As part of a comprehensive treatment programme for Attention Deficit/Hyperactivity Disorder (ADHD) in children aged 6 years and over and adolescents when remedial measures alone prove insufficient. Treatment must be under the supervision of a specialist in childhood behavioural disorders.

Presentation: 18mg tablet contains 18mg methylphenidate hydrochloride (equivalent to 15.57mg methylphenidate). 27mg: contains 27mg methylphenidate hydrochloride (equivalent to 23.35mg methylphenidate). 36mg contains 36mg methylphenidate hydrochloride (equivalent to 31.13mg methylphenidate) 54mg contains 54mg methylphenidate hydrochloride (equivalent to 46.7mg methylphenidate).

Dosage and administration: Tablets for oral use, to be taken once daily. Swallowed whole with sufficient liquid, with or without food, and must not be chewed or crushed. 27mg, 36mg and 54mg tablets can be divided into equal doses. Pre-treatment screening: A baseline evaluation of the patient's cardiovascular status including blood pressure and heart rate, 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. Dose titration: Start at the lowest possible dose. Dose may be adjusted in 18mg increments at approximately weekly intervals. Patients new to methylphenidate: Consider lower doses of short-acting methylphenidate formulations. Patients currently using methylphenidate: Recommended dose conversion from 5, 10, 15mg three times daily is 18, 36, 54mg of Xenidate XL once daily, respectively. Discontinue treatment if improvement not observed over a one-month period after dosage adjustment.

Contraindications: Hypersensitivity to the active substances or to any of the excipients. 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 (severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies) and cerebrovascular disorders (e.g. cerebral aneurysm, vascular abnormalities including vasculitis and stroke).

Warning and precautions: Long term use (more than 12 months) ongoing monitoring (at each dose adjustment and then at least every 6 months) for cardiovascular status (blood pressure and pulse); neurological signs and symptoms (cerebrovascular disorders and additional risk factors); 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 Xenidate may lower convulsive threshold); growth (height, weight and appetite). Patients 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. Methylphenidate must be discontinued as soon as possible if serotonin syndrome is suspected. Contains sucrose.

Pregnancy and lactation: Not recommended for use during pregnancy. Discontinue in breast-feeding, methylphenidate has been found in breast milk.

Effects on ability to drive and use machines: Dizziness, drowsiness and visual disturbances including difficulties with accommodation, diplopia and blurred vision. Can cause impairment of cognitive function and can affect a patient's ability to drive safely.

Undesirable effects: Very common (=1/10): Insomnia, nervousness, headache. Common (=1/100 to <1/10): Nasopharyngitis, upper respiratory tract infection, sinusitis, decreased appetite, moderately reduced weight and height gain during prolonged use in children, anorexia, affect-lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, mood swings, tics, initial insomnia, depressed mood, libido decreased, tension, bruxism, panic attack, dizziness, dyskinesia, psychomotor hyperactivity, somnolence, paraesthesia, tension headache, accommodation disorder, vertigo, arrhythmia, tachycardia, palpitations, hypertension, cough, oropharyngeal pain, abdominal pain upper, diarrhoea, nausea, abdominal discomfort, vomiting, dry mouth, dyspepsia, alopecia, pruritis, rash, urticaria, arthralgia, muscle tightness, muscle spasms, 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, erectile dysfunction for 27mg only.

Other serious side effects: hyper-sensitivity reactions such as angio-neurotic oedema, anaphylactic reactions, auricular swelling, bullous conditions, exfoliative conditions, psychotic disorders, visual and tactile hallucination, suicidal ideation, worsening of pre-existing, logorrhea, cardiac murmur, mania, suicidal attempt (including completed suicide), transient depressed mood, neuroleptic malignant syndrome, cardiac arrest, myocardial infarction, abnormal liver function, including hepatic coma, delusions, cerebro-vascular disorders (including vasculitis, cerebral haemorrhages, cerebro-vascular accidents, cerebral occlusion).

Legal Category: POM

Marketing Authorisation Number: PL 04569/1417, 1605, 1418-19

MAH: Generics [UK] Limited t/a Mylan, Station Close, Potters Bar, Herts, EN6 1TL, UK

Price: 30 tablets 18mg = 15.57; 27mg = 18.39; 36mg = 21.21; 54mg = 36.79

Date of Revision of Prescribing Information: March 2019

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 Viatris Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info@viatris.co.uk

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should be reported to Viatris, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, on phone no. +44 (0) 800 121 8267, Email: ukpharmacovigilance@viatris.com