EQUASYM XL (methylphenidate hydrochloride) 10mg, 20mg and 30mg Modified-Release Capsules, Hard.
PRESCRIBING INFORMATION FOR GREAT BRITAIN (ENGLAND, SCOTLAND, WALES) AND NORTHERN IRELAND
Refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: Each capsule contains 10 mg, 20 mg and 30 mg methylphenidate hydrochloride, corresponding to 8.65 mg, 17.30 mg and 25.94 mg of methylphenidate. **Indication:** Attention-deficit hyperactivity disorder (ADHD) in children aged 6 years and over as part of a comprehensive treatment programme under the supervision of a specialist in childhood behavioural disorders where remedial measures alone prove insufficient. **Dosage and administration:** Paediatric population (Children (aged 6 years and over) and adolescents): Prior to prescribing, it is necessary to conduct an evaluation of cardiovascular status, psychiatric status and height and weight. *New patients*: The starting dose is 10mg taken before breakfast. Careful dose titration is necessary. The maximum daily dose is 60mg. *Patients currently using methylphenidate*: A 20mg dose of Equasym XL is intended to replace 10mg of immediate release methylphenidate taken at breakfast and lunchtime. Ongoing monitoring: Growth, psychiatric and cardiovascular status should be continuously monitored: Blood pressure and pulse should be recorded on a centile chart at each adjustment of dose and then at least every 6 months. Height, weight and appetite should be recorded at least 6-monthly with maintenance of a growth chart. Development of *de novo* or worsening of pre-existing psychiatric disorders should be monitored at every adjustment of dose and then least every 6 months and at every visit. Patients should be monitored for the risk of diversion, misuse and abuse of methylphenidate. Administration: The capsules may be swallowed whole with liquid, or the contents may be sprinkled onto soft food e.g. apple sauce and swallowed immediately, followed by a drink. The capsules and their contents must not be crushed or chewed. Adults and elderly: Safety and efficacy not established. Children under 6 years of age: Safety and efficacy not established. Long-term Use: Long-term use (i.e. over 12 months) has not been evaluated in controlled trials. The continued usefulness of the drug should be re-evaluated at least yearly by trial periods off medication to assess the patient's functioning without pharmacotherapy. **Contraindications:** Hypersensitivity to methylphenidate or excipients; glaucoma, phaeochromocytoma, hyperthyroidism, thyrotoxicosis, treatment with non-selective irreversible monoamine oxidase inhibitors (or within 14 days of their discontinuation), 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, 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. **Warnings and precautions:** Monitor cardiovascular status carefully as sudden cardiac or unexplained death has been reported. Monitor psychiatric status as treatment may exacerbate symptoms in psychotic children, or may precipitate mixed/manic episodes. Equasym XL is associated with worsening or emergence of aggressive behaviour, emergent suicidal ideation or behaviour, onset or exacerbation of tics, worsening of Tourette's syndrome, worsening of pre-existing anxiety, agitation or tension. Use with caution in those with epilepsy as may increase frequency of seizures. Priapism has been reported in association with methylphenidate products, mainly in association with a change in treatment regimen. Monitor abuse potential as chronic abuse may lead to tolerance and dependency with abnormal behaviour. Monitor weight, growth, blood pressure and pulse. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take Equasym XL. Supervise drug withdrawal. Should not be used for treatment or prevention of normal fatigue states. There is no experience with the use of methylphenidate in patients with renal or hepatic insufficiency. Haematological effects indicative of serious renal or hepatic disorders, discontinuation of treatment should be considered. **Interactions:** Drugs that elevate blood pressure, anticonvulsants (e.g. phenobarbital, phenytoin, primidone), tricyclics and SSRIs, coumarin anticoagulants, clonidine and other alpha-2 agonists, anti-hypertensives, halogenated anaesthetics, alcohol, dopamine agonists or antagonists including antipsychotics. **Fertility, pregnancy and lactation:** Equasym XL is not recommended during pregnancy. Equasym XL has been found in breast milk and should not be used during breast feeding. **Effects on ability to drive and use machines:** Equasym XL may impair ability to drive or operate machinery. Patients should be warned not to drive or operate machinery until they know how the medicine affects them. **Undesirable effects:** *Very common (≥1/10 patients):* Nervousness, insomnia, headache. *Common (≥1/100, <1/10 patients):* Arrhythmia, palpitations, tachycardia, hypertension, abdominal pain, nausea, diarrhoea, stomach discomfort and vomiting, dry mouth, changes in blood pressure and heart rate, decreased appetite, moderately reduced weight and height gain during prolonged use, growth retardation

during prolonged use, pyrexia, arthralgia, dizziness, dyskinesia, abnormal behaviour, bruxism, aggression, agitation, anorexia, anxiety, depression, irritability, alopecia, rash, pruritus, urticaria, nasopharyngitis, affect lability, psychomotor hyperactivity, somnolence, sedation, tremor, cough, pharyngolaryngeal pain. Other *Serious undesirable effects:* Thrombocytopenia, pancytopenia, anaphylactic reactions, psychotic disorders, auditory, visual and tactile hallucinations, suicidal ideation, Tourette's syndrome, suicidal attempt (including completed suicide), dependence, neuroleptic malignant syndrome (NMS), vasculitis, cerebral haemorrhages, cerebrovascular accidents, cerebral arteritis, cerebral occlusion, grand mal convulsions, angina pectoris, cardiac arrest, myocardial infarction, bradycardia, cerebral arteritis, erythema multiforme, erectile dysfunction, sudden cardiac death, hyperpyrexia. **Refer to the SmPC for details on full side effect profile and interactions. UK Basic NHS price:** (for 30 capsules) 10mg: £25.00, 20mg: £30.00, 30mg: £35.00 **Legal Classification:** CD (Sch 2) POM. **Marketing authorisation (MA):** GB & NI: 10 mg: PL 54937/0001, 20 mg: PL 54937/0002, 30 mg: PL 54937/0003**. Business responsible for sale and supply:** GB & NI: Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. **PI approval code:** pi-02003. **Date of preparation:** June 2022. EQUASYM XL is a registered trade name.

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 Takeda at: AE.GBR-IRL@takeda.com.