PRESCRIBING INFORMATION Please refer to Summary of Product Characteristics (SmPC) before prescribing MEFLYNATE® XL 10-60mg modified-release capsules, hard.

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

ACTIVE INGREDIENT: Methylphenidate hydrochloride 10, 20, 30, 40 or 60mg.

INDICATIONS: Attention-deficit hyperactivity disorder (ADHD) in children aged 6 years and over and adults as part of a comprehensive treatment programme when remedial measures alone prove insufficient. Treatment must be initiated and supervised by a doctor specialised in the treatment of ADHD.

DOSAGE and ADMINISTRATION:
Pre-treatment screening: Conduct baseline evaluation of cardiovascular status, including blood pressure and heart rate. A comprehensive history should document concomitant medications, past and present comorbid medical and psychiatric disorders or symptoms, family history of sudden/unexplained death and pre-treatment height (in children only) and weight on a growth chart.

Dose titration:
Children (6 years and over): Careful dose titration necessary at start of treatment. Recommended starting dose 20mg once daily in the morning unless initial dose of 10mg considered appropriate. Short-acting methylphenidate can be used at the start of treatment and increased according to the formulation's recommendations. Maximum daily dose in children is 60mg**.**
Adults: Start at 20mg once daily in the morning and titrate in 20mg increments at weekly intervals. Use only modified-release formulations of methylphenidate to treat ADHD in adults. Maximum daily dose in adults is 80mg.
Adult patients new to methylphenidate: Recommended starting dose is 20 mg once daily. Dose may be adjusted weekly in 20 mg increments for adults. Other strengths of Meflynate XL or other methylphenidate preparations can be used to achieve lower doses or smaller increments.
Patients transitioning from childhood methylphenidate treatment to adulthood: Treatment may be continued with same daily dose. Patients established on immediate-release methylphenidate can be switched to mg equivalent daily dose of Meflynate XL.
Switching patients: Patients taking immediate-release methylphenidate twice daily can be switched to mg equivalent daily dose of Meflynate XL.

Administration:
Oral use once daily in the morning with, or without, food. Swallow capsules whole or sprinkle contents onto small amount of unwarmed, soft food. Consume entire mixture immediately. The capsule and contents must not be crushed or chewed.

CONTRAINDICATIONS: Hypersensitivity 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 disorder, 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:

Long-term use (more than 12 months): Long-term use has not been evaluated in controlled trials. Patients must have ongoing monitoring for cardiovascular status, growth (children), weight, appetite, development of *de novo* or worsening of pre-existing psychiatric disorders. Periodically re-evaluate usefulness. Annual de-challenge.

Use in patients >60 years: Should not be used. Safety and efficacy not established.

Children under 6 years: Should not be used. Safety and efficacy not established.

Cardiovascular status

- Specialist cardiac evaluation prior to treatment if initial assessment suggests history or presence of cardiac disease. Seek prompt specialist evaluation if symptoms suggestive of cardiac disease develop during treatment.
- Sudden or unexplained death have been reported with use of stimulants.
- Caution with underlying medical conditions that might be compromised by increases in blood pressure or heart rate.
- Assess neurological signs and symptoms at every visit in patients at risk of cerebrovascular disorders.

Conduct a baseline assessment then monitor at every dose adjustment, then at least every 6 months and at every visit:

  - cardiovascular status, blood pressure and pulse,
  - development or worsening of psychiatric disorders,
  - emergence or worsening of pre-existing psychotic symptoms or mania,
  - emergence or worsening of aggressive or hostile behaviour,
  - onset or exacerbation of tics,
  - emergence or worsening of Tourette's syndrome,
  - worsening of pre-existing anxiety, agitation or tension,
  - comorbid bipolar disorder and patients with comorbid depressive symptoms at risk for bipolar disorder.

- Evaluate patients with emergent suicidal ideation or behaviour immediately
- In children, record height, weight and appetite at least 6 monthly on a growth chart.
- Regularly monitor weight in adults.
- Caution in patients with epilepsy and in patients with prior EEG abnormalities. Discontinue if seizure frequency increases or new onset seizures occur.
- Monitor for risk of abuse, misuse and diversion. Use with caution in patients with known drug or alcohol dependency. Consider previous, or current, substance abuse and risk factors for substance use disorder.
- Carefully supervise drug withdrawal, including from abusive use since severe depression may occur.
- Not to be used for the prevention or treatment of normal fatigue states.
- There is no experience with use in renal or hepatic insufficiency.
- In the event of leukopenia, thrombocytopenia, anaemia or other haematological effects, including those indicative of serious renal or hepatic disorders, consider discontinuation of treatment.
- Seek immediate medical attention for sustained or frequent painful erections.
- May induce false positive results for amfetamines during drug testing.
- Patients with fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Meflynate XL.

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 (including DOPA and tricyclic antidepressants) or dopamine antagonists (including antipsychotics) and antacids.

PREGNANCY, LACTATION and FERTILITY: Methylphenidate is not recommended in pregnancy and should not be used by breastfeeding mothers when the risk to the child outweighs the benefit of therapy to the mother. No data available on the effect of methylphenidate on fertility.

DRIVING: Avoid driving or operating machinery if affected by dizziness, drowsiness and visual disturbances.

UNDESIRABLE EFFECTS: **Very common:** Decreased appetite, insomnia, nervousness, headache, nausea, dry mouth. **Common:** Nasopharyngitis, anorexia, reduced weight and height gain during prolonged use in children, weight decrease in adults, affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, restlessness, sleep disorder, decreased libido, panic attack, stress, bruxism, tremor, somnolence, dizziness, dyskinesia, psychomotor hyperactivity, arrhythmia, palpitations, tachycardia, hypertension, peripheral coldness, cough, pharyngolaryngeal pain, dyspnoea, abdominal pain, diarrhoea, stomach discomfort, vomiting, dyspepsia, toothache, hyperhidrosis, alopecia, pruritus, rash, urticaria, arthralgia, pyrexia, feeling jittery, fatigue, thirst, changes in blood pressure and heart rate. **Other side-effects:** hypersensitivity reactions, erythema multiforme, psychotic disorders, delusions, suicidal ideation/ attempt/ completion, neuroleptic malignant syndrome, cerebrovascular disorders, cerebrovascular accidents, convulsions, angina pectoris, cardiac arrest, myocardial infarction, sudden cardiac death, abnormal liver function including hepatic coma, anaemia, leukopenia, thrombocytopenia, pancytopenia, priapism, hyperpyrexia. **Consult SmPC for all side effects.**

PHARMACEUTICAL PRECAUTIONS: No special storage conditions.

LEGAL CATEGORY: CD (Sch 2) POM.

Product	NHS Cost (for 30 pack)	Marketing Authorisation Number
Meflynate XL 10mg	£17.50	PL13621/0090
Meflynate XL 20mg	£21.00	PL13621/0091
Meflynate XL 30mg	£24.50	PL13621/0092
Meflynate XL 40mg	£40.40	PL13621/0093
Meflynate XL 60mg	£47.40	PL13621/0094

MARKETING AUTHORISATION HOLDER:
Flynn Pharma Limited
5th Floor
40 Mespil Road
Dublin 4
Ireland, DO4 C2N4

Marketed in the UK by Flynn Pharma Ltd, Hertlands House, Primett Road, Stevenage, Herts, SG1 3EE.
Tel: 01438 727822 Email: medinfo@flynnpharma.com
Meflynate XL is a registered trademark of Flynn Pharma Limited

DATE OF PREPARATION OF PRESCRIBING INFORMATION: August 2023