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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Varenicline 0.5mg and 1mg Film-Coated Tablets Abbreviated Prescribing Information **Presentation:** Each film-coated tablet contains 0.5mg and 1mg of Varenicline (as tartrate). **Indications:** Smoking cessation in adults. **Dosage and administration:** Oral use. *Adults*: The recommended dose is 1mg Varenicline twice daily following a 1-week titration (see SmPC for details). *Children*: Not recommended for use. *Elderly:* No dosage adjustment is necessary. Elderly patients are more likely to have decreased renal function, prescribers should consider the renal status of an elderly patient. *Renal impairment:* No dosage adjustment is necessary for patients with mild (estimated creatinine clearance >50ml/min and ≤80ml/min) to moderate (estimated creatinine clearance ≥30ml/min and ≤50ml/min) renal impairment. For patients with severe renal impairment (estimated creatinine clearance <30ml/min), the recommended dose of Varenicline is 1mg once daily. *Hepatic impairment:* No dosage adjustment is necessary. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** Physiological changes resulting from smoking cessation, with or without treatment with Varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with Varenicline. Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment. If serious neuropsychiatric symptoms occur whilst on Varenicline treatment, patients should discontinue Varenicline immediately and contact a healthcare professional for re-evaluation of treatment. Smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression). In clinical trials and post-marketing experience there have been reports of seizures in patients with or without a history of seizures, treated with Varenicline. Varenicline should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold. At the end of treatment, discontinuation of Varenicline was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients. In such instances, tapering should be considered. Patients taking Varenicline should seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke. Hypersensitivity reactions including angioedema (swelling of the face, mouth neck and extremities) have been reported in patients treated with varenicline. Some rare life-threatening reports required urgent medical attention due to respiratory compromise. Rare and severe cutaneous reactions (Stevens-Johnson-Syndrome and Erythema Multiforme) have also been reported in post-marketing reports. Due to the life-threatening nature of these conditions, varenicline should be discontinued and a healthcare provider should be contacted immediately. **Interactions:** Varenicline has no clinically meaningful drug interactions (see SmPC for further details). No dosage adjustment of Varenicline or co-administered medicinal products listed below is recommended. *In vitro* studies indicate that Varenicline is unlikely to alter the pharmacokinetics of compounds that are primarily metabolised by cytochrome P450 enzymes. Furthermore, since metabolism of Varenicline represents less than 10% of its clearance, active substances known to affect the cytochrome P450 system are unlikely to alter the pharmacokinetics of Varenicline, therefore a dose adjustment of Varenicline would not be required. Varenilcine is not known to affect the pharmacokinetics of metformin, digoxin, bupropion and warfarin. Co-administration of cimetidine, with Varenicline increased the systemic exposure of varenicline by due to a reduction in varenicline renal clearance. In patients with severe renal impairment, the concomitant use of cimetidine and Varenicline should be avoided. **Pregnancy and lactation:** As a precautionary measure, it is preferable to avoid the use of varenicline during pregnancy. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with varenicline should be made taking into account the benefit of breast-feeding to the child and the benefit of varenicline therapy to the woman. **Effects on ability to drive and use machines:** Varenicline may have minor or moderate influence on the ability to drive and use machines. Varenicline may cause dizziness, somnolence and transient loss of consciousness, and therefore may influence the ability to drive and use machines. **Adverse reactions:** Diabetes mellitus, suicidal ideation, depression, hallucinations, psychosis, seizure, cerebrovascular accident, transient loss of consciousness, myocardial infarction, angina pectoris, tachycardia, atrial fibrillation, electrocardiogram ST segment depression, gastritis, haematemesis, severe cutaneous reactions including Stevens Johnson Syndrome and Erythema Multiforme, angioedema. *Very Common*: Nasopharyngitis, abnormal dreams, insomnia, headache, nausea. *Common:* Bronchitis, sinusitis, weight increased, decreased appetite, increased appetite, somnolence,

dizziness, dysgeusia, dyspnoea, cough, gastroesophageal reflux disease, vomiting, constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth, rash, pruritus, arthralgia, myalgia, back pain, chest pain, fatigue, liver function test abnormal. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** In case of overdose, standard supportive measures should be instituted as required. **List Price:** *Wave Pharma Limited:* 0.5mg, pack of 28: £23.21; 1mg, pack of 28: £23.21. *Brown & Burk UK Ltd:* 0.5mg, pack of 56: £46.41; 1mg, pack of 28: £23.21; Combination 0.5mg and 1mg, pack of 25: £23.21. Not all pack sizes may be marketed. **Legal category:** POM. **Marketing Authorisation Number:** *Wave:* 0.5mg PL 42289/0026 and 1mg PL 42289/0027. *Brown & Burk:* 0.5mg PL 25298/0386, 1mg PL 25298/0387, 0.5mg & 1mg PL 25298/0410. **Marketing Authorisation Holder:** Wave Pharma Limited., Ground Floor, Cavendish House, 369 Burnt Oak, Broadway, Edgware, HA8 5AW, UK. Or Brown & Burk UK Ltd, Micro House 5 Marryat Close, Hounslow TW4 5DQ, UK. **Job Code:** MED-GB-00449. **Date of Preparation:** May 2025