CHAMPIX® Film-Coated Tablets (varenicline tartrate)
ABBREVIATED PRESCRIBING INFORMATION – UK
(See Champix Summary of Product Characteristics for full Prescribing Information)
Please refer to the SmPC before prescribing Champix 0.5 mg and 1 mg.
Presentation: White, capsular-shaped, biconvex tablets debossed with *"Pfizer"* on one side and "CHX 0.5" on the other side and light blue, capsular-shaped, biconvex tablets debossed with *"Pfizer"* on one side and "CHX 1.0" on the other side. **Indications:** Champix is indicated for smoking cessation in adults. **Dosage:** The recommended dose is 1 mg varenicline twice daily following a 1-week titration as follows: Days 1-3: 0.5 mg once daily, Days 4-7: 0.5 mg twice daily and Day 8 – End of treatment: 1 mg twice daily. The patient should set a date to stop smoking. Dosing should usually start 1-2 weeks before this date. Patients who are not willing or able to set the target quit date within 1-2 weeks, could be offered to start treatment and then choose their own quit date within 5 weeks. Patients should be treated with Champix for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment at 1 mg twice daily may be considered for the maintenance of abstinence. A gradual approach to quitting smoking with Champix should be considered for patients who are not able or willing to quit abruptly. Patients should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period. Patients should then continue taking Champix for an additional 12 weeks for a total of 24 weeks of treatment. Patients who are motivated to quit and who did not succeed in stopping smoking during prior Champix therapy, or who relapsed after treatment, may benefit from another quit attempt with Champix. Patients who cannot tolerate adverse effects may have the dose lowered temporarily or permanently to 0.5 mg twice daily. Following the end of treatment, dose tapering may be considered in patients with a high risk of relapse. Renal impairment; *Mild to moderate renal impairment:* No dosage adjustment is necessary. *Patients with moderate renal impairment* who *experience intolerable adverse events:* Dosing may be reduced to 1 mg once daily. *Severe renal impairment:* 1 mg once daily is recommended. Dosing should begin at 0.5 mg once daily for the first 3 days then increased to 1 mg once daily. *End stage renal disease:* Treatment is not recommended. Hepatic impairment and elderly patients; No dosage adjustment is necessary. Paediatric patients; Not recommended in patients below the age of 18 years. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** *Effect of smoking cessation;* Stopping smoking may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). 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 Champix in the post-marketing experience. A large randomised, double-blind, active and placebo-controlled study was conducted to compare the risk of serious neuropsychiatric events in patients with and without a history of psychiatric disorder treated for smoking cessation with varenicline, bupropion, nicotine replacement therapy patch (NRT) or placebo. The primary safety endpoint was a composite of neuropsychiatric adverse events that have been reported in post-marketing experience. The use of varenicline in patients with or without a history of psychiatric disorder was not associated with an increased risk of serious neuropsychiatric adverse events in the composite primary endpoint compared with placebo. 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). Champix smoking cessation studies have provided data in patients with a history of psychiatric disorders. In a smoking cessation clinical trial, neuropsychiatric adverse events were reported more frequently in patients with a history of psychiatric disorders compared to those without a history of psychiatric disorders, regardless of treatment. Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly. Patients taking Champix should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke. In clinical trials and post-marketing experience there have been reports of seizures in patients with or without a history of seizures, treated with Champix. Champix 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 Champix was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients, therefore dose tapering may be considered. There have been post-marketing reports of hypersensitivity reactions including angioedema and reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using varenicline. Patients experiencing these symptoms should discontinue treatment with varenicline and contact a health care provider immediately. **Fertility, pregnancy and lactation:** A moderate amount of data on pregnant women indicated no malformative or foetal/neonatal toxicity of varenicline. Animal studies have shown reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of varenicline during pregnancy. It is unknown whether varenicline is excreted in human breast milk. Animal studies suggest that varenicline is excreted in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Champix should be made taking into account the benefit of breast-feeding to the child and the benefit of Champix therapy to the woman. There are no clinical data on the effects of varenicline on fertility. Non-clinical data revealed no hazard for humans based on standard male and female fertility studies in the rat. **Driving and operating machinery:** Champix may have minor or moderate influence on the ability to drive and use machines. Champix may cause dizziness, somnolence and transient loss of consciousness, and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities. **Side-Effects:** Very commonly reported side effects were nasopharyngitis, abnormal dreams, insomnia, headache and nausea. Commonly reported side-effects were bronchitis, sinusitis, weight increased, decreased appetite, increased appetite, somnolence, dizziness, dysgeusia, dyspnoea, cough, gastrooesophageal reflux disease, vomiting, constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth, rash, pruritis, arthralgia, myalgia, back pain, chest pain, fatigue and abnormal liver function tests. Other side effects were, diabetes mellitus, suicidal ideation, aggression, psychosis, seizures, cerebrovascular accident, angina pectoris, atrial fibrillation, electrocardiogram ST segment depression, myocardial infarction, electrocardiogram T wave amplitude decreased, haematemesis, haematochezia, decreased platelet count, severe cutaneous reactions, including Stevens Johnson Syndrome and erythema multiforme, and angioedema. For full list of side effects see SmPC. **Overdose:** Standard supportive measures to be adopted as required. Varenicline has been shown to be dialyzed in patients with end stage renal disease, however, there is no experience in dialysis following overdose. **Legal category**: POM. **Basic NHS cost:** Pack of 25 11 x 0.5 mg and 14 x 1mg tablets Card (EU/1/06/360/014) £27.30 Pack of 28 1mg tablets Card (EU/1/06/360/015) £27.30 Pack of 56 0.5 mg tablets HDPE Bottle (EU/1/06/360/001) £54.60 Pack of 56 1mg tablets Card (EU/1/06/360/016) £54.60 Pack of 53 11 x 0.5 mg and 42 x 1mg tablets Card (EU/1/06/360/023) £54.60. Not all pack sizes may be marketed/marketed at launch. **Marketing Authorisation Holder**: Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. **Further information on request**: Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS.
Last revised: 08/2018.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Pfizer Medical Information on 01304 616161

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