As well as relieving nicotine cravings, nicotine intake stimulates the brain to produce feelings of pleasure. CHAMPIX is a non-nicotine treatment that works in two ways to help patients quit smoking.

**How does it work?**

- CHAMPIX action 1: blocks nicotine from binding to a receptor in the brain.
- CHAMPIX action 2: releases reduced level of dopamine vs. nicotine.
- CHAMPIX effect 1: reduces satisfaction, taste and enjoyment of smoking.
- CHAMPIX effect 2: reduces cravings and withdrawal symptoms.

Nicotine travels quickly to the brain and enters the bloodstream. CHAMPIX blocks nicotine from binding to a receptor in the brain, releasing a reduced level of dopamine compared to nicotine. CHAMPIX reduces cravings and withdrawal symptoms, reducing satisfaction, taste and enjoyment of smoking.

*Dopamine released leading to a feeling of pleasure.*

*Drop in dopamine leads to withdrawal symptoms of irritability and restlessness.*

*Desire for another cigarette to release more dopamine to relieve withdrawal symptoms.*

*Nicotine travels quickly to the brain.*

*Smoking delivers nicotine.*

*Nicotine enters the bloodstream.*

*The three components that make up the smoking satisfaction domain measured by the Modified Cigarette Evaluation Questionnaire are satisfaction, taste and enjoyment.*

*CHAMPIX is a non-nicotine treatment that works in two ways to help patients quit smoking.*
Prescribing information

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 “CH 0.5” on the other side and light blue, capsular-shaped, biconvex tablets debossed with “Pfizer” on one side and “CH 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 who cannot tolerate adverse effects may have the dose lowered temporarily or permanently to 0.5 mg twice daily. 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. 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. Following the end of treatment, dose tapering may be considered in patients with a high risk of relapse. Patients with renal impairment: Mild to moderate renal impairment: No dosage adjustment is necessary. Patients with moderate renal 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: 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 behavior, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with Champix in the post-marketing experience. Not all patients had stopped smoking at the time of onset of symptoms and not all patients had known pre-existing psychiatric illness. Champix should be discontinued immediately if agitation, depressed mood or changes in behaviour or thinking that are of concern for the doctor, the patient, family or caregivers are observed, or if the patient develops suicidal ideation or suicidal behaviour. In many post-marketing cases, resolution of symptoms after discontinuation of varenicline was reported, although in some cases the symptoms persisted; therefore, ongoing follow up should be provided until symptoms resolve. Depression, mood, rarely including suicidal ideation, and suicide attempt, may be a symptom of nicotine withdrawal. In addition, smoking cessation, with or without pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). In a trial of patients with stable cardiovascular disease ICVD) certain cardiovascular events were reported more frequently in patients treated with CHAMPIX. A meta-analysis of 15 clinical trials, which included the smoking cessation trial of patients with stable CVD, had similar results. 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. Champix smoking cessation studies have provided data in patients with major depressive disorder and limited data in patients with stable schizophrenia or schizoaffective disorder. Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly. 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 psychiatric illness and patients should be advised accordingly. 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. 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. Pregnancy and lactation: Champix should not be used during pregnancy. It is unknown whether varenicline is excreted in human breast milk. Champix should only be prescribed to breastfeeding mothers when the benefit outweighs the risk. 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. Patients should be advised that dizziness 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: Adverse reactions during clinical trials were usually mild to moderate. 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, dysphonia, cough, gastroesophageal 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, seizures, cerebrovascular accident, angina pectoris, atrial fibrillation, electrocardiogram ST segment depression, myocardial infarction, haematemesis, haematocheia, Stevens-Johnson Syndrome, angioedema and decreased platelet count. For full list of side effects see SmPC. Overdose: Standard supportive measures to be adopted as required. Varenicline has been shown to be dialysed 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 x 0.5 mg and 14 x 1 mg tablets Card (EU/1/06/360/014) £24.30. Pack of 28 x 1mg Tablets Card (EU/1/06/360/015) £27.30. Pack of 56 x 0.5 mg tablets HDP Bottles (EU/1/06/360/001) E54.60. Pack of 56 x 1mg tablets Card (EU/1/06/360/016) E54.60. Not all pack sizes may be marketed / marketed at launch. Marketing Authorisation Holder: Pfizer Limited, Sandwich, Kent, CT3 3NJ, United Kingdom. Further information on request. Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS. Last reviewed: 02/2014. Ref. C16_0.

Adverse events should be reported. Reporting forms and information can be found on www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Pfizer Medical Information on 01304 616161

References