SCHEDULING STATUS: S5

1. NAME OF THE MEDICINE

CHAMPIX® 0,5 mg Film-coated tablets

CHAMPIX® 1 mg Film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 0,5 mg or 1 mg of varenicline (as tartrate).

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

CHAMPIX 0,5 mg film-coated tablets: Capsular biconvex, white to off-white film-coated tablet, debossed "*Pfizer*" on one side and "CHX 0.5" on the other side.

CHAMPIX 1 mg film-coated tablets: Capsular biconvex, light blue film-coated tablet, debossed "*Pfizer*" on one side and "CHX 1.0" on the other side.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

CHAMPIX is indicated as an aid to smoking cessation in patients committed to stop smoking, in addition to a behaviour modification programme, for 12 weeks.

4.2. Posology and method of administration

All smoking cessation therapies are more likely to succeed in patients who are motivated to stop smoking and who are provided with additional advice and continuous support.

Patients should be treated with CHAMPIX for 12 weeks.

Posology

The recommended dose of CHAMPIX is 1 mg twice daily following a 1-week titration as follows:

Days 1 – 3:	0,5 mg once daily in the evening
Days 4 – 7:	0,5 mg twice daily
Day 8 – End of treatment:	1 mg twice daily

The patient should set the date to stop smoking. CHAMPIX dosing should start 1 – 2 weeks before this date.

Patients who do not succeed in stopping smoking during 12 weeks of initial therapy, or who relapse after treatment, should be encouraged to make another attempt once factors contributing to the failed attempt have been identified and addressed.

For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with CHAMPIX 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 cannot tolerate adverse reactions of CHAMPIX may have the dose lowered temporarily or permanently.

Dose tapering of CHAMPIX is not required at the end of treatment.

Special populations

Patients with renal insufficiency

No dosage adjustment is necessary for patients with mild (estimated creatinine clearance > 50 mL/min and ≤ 80 mL/min) to moderate (estimated creatinine clearance ≥ 30 mL/min and ≤ 50 mL/min) renal impairment.

For patients with severe renal impairment, the recommended dose of CHAMPIX is 1 mg once daily. Dosing should begin at 0,5 mg once daily for the first 3 days then increased to 1 mg once daily. There is insufficient clinical experience with CHAMPIX in patients with end stage renal disease (see section 5.2).

Patients with hepatic impairment

No dosage adjustment is necessary for patients with hepatic impairment (see section 5.2).

Use in elderly patients

No dosage adjustment is necessary for elderly patients (see section 5.2). Because elderly patients are more likely to have decreased renal function, medical practitioners should consider the renal status of an elderly patient.

Paediatric population

Safety and effectiveness of CHAMPIX in paediatric patients have not been established; therefore, CHAMPIX is not recommended for use in patients under 18 years of age (see section 5.2).

Method of administration

For oral use and the tablets should be swallowed whole with water.

CHAMPIX can be taken with or without food.

4.3 Contraindications

Hypersensitivity to varenicline or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Effect of smoking cessation

Physiological changes resulting from smoking cessation, with or without treatment with CHAMPIX, may alter the pharmacokinetics or pharmacodynamics of some medicines, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). However, in post-marketing data there were cases of increased international normalised ratio (INR). INR should be monitored more frequently, and the warfarin dose adjusted while using CHAMPIX, and after discontinuation of CHAMPIX (see section 4.5).

Neuropsychiatric symptoms and suicidality

Serious neuropsychiatric symptoms have been reported in patients being treated with CHAMPIX. These post-marketing reports have included changes in behaviour or thinking, changes in mood (including depression and mania), aggressive behaviour, psychosis, hallucinations, paranoia, delusions, homicidal ideation, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide (see section 4.8 – Post-marketing experience). Some reported cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking CHAMPIX who continued to smoke. When symptoms were reported, most were during CHAMPIX treatment, but some were following discontinuation of CHAMPIX therapy. These events have occurred in patients with and without pre-existing psychiatric disease; some patients have experienced worsening of their psychiatric illnesses. All patients being treated with CHAMPIX should be observed for neuropsychiatric symptoms or worsening of pre-existing psychiatric illness.

Advise patients and caregivers that the patient should stop taking CHAMPIX and contact a medical practitioner immediately if agitation, depressed mood, changes in behaviour or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behaviour. In many post-marketing cases, resolution of symptoms after discontinuation of CHAMPIX was reported, although in some cases the symptoms persisted, therefore, ongoing monitoring and

supportive care should be provided until symptoms resolve.

Medical practitioners 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 CHAMPIX, patients should discontinue CHAMPIX immediately and contact a medical practitioner for re-evaluation of treatment.

Seizures

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.

Treatment discontinuation

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.

Angioedema and hypersensitivity reactions

There have been post-marketing reports of hypersensitivity reactions including angioedema in patients treated with CHAMPIX (see section 4.8 – Post-marketing experience). Clinical signs included swelling of the face, mouth (tongue, lips, and gums), extremities, and neck (throat and larynx). There were reports of life-threatening angioedema requiring urgent medical attention due to respiratory compromise. Patients should be instructed to discontinue CHAMPIX and immediately seek medical care if they experience these symptoms.

Serious skin reactions

There have been post-marketing reports of serious skin reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using CHAMPIX (see section 4.8 – Post-marketing experience). As these skin reactions can be life-threatening, patients should be instructed to stop taking CHAMPIX and contact their medical practitioner immediately at the first appearance of a skin rash with mucosal lesions or any other signs

of hypersensitivity.

Cardiovascular effects

In a smoking cessation trial of patients with stable cardiovascular disease, 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 cardiovascular disease, had similar results. Cardiovascular events occurred primarily in patients with known cardiovascular disease. Patients should be instructed to notify their medical practitioners of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.

4.5 Interaction with other medicines and other forms of interaction

Based on varenicline characteristics and clinical experience to date, CHAMPIX has no clinically meaningful medicine interactions. No dosage adjustment of CHAMPIX or co-administered medicine listed below is recommended.

In vitro studies demonstrate that CHAMPIX does not inhibit cytochrome P450 enzymes (IC50 > 6 400 ng/mL). The P450 enzymes tested for inhibition were: 1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6, 2E1, and 3A4/5. Also, in human hepatocytes *in vitro*, CHAMPIX was shown to not induce the activity of cytochrome P450 enzymes 1A2 and 3A4. Therefore, CHAMPIX is unlikely to alter the pharmacokinetics of compounds that are primarily metabolised by cytochrome P450 enzymes.

Furthermore, since metabolism of CHAMPIX represents less than 10 % of its clearance, active substances known to affect the cytochrome P450 system are unlikely to alter the pharmacokinetics of CHAMPIX and therefore a dose adjustment of CHAMPIX would not be required.

In vitro studies demonstrate that CHAMPIX does not inhibit human renal transport proteins at therapeutic concentrations. Therefore, medicines that are cleared by renal secretion (e.g. metformin – see below) are unlikely to be affected by CHAMPIX.

In vitro studies demonstrate that active renal secretion of CHAMPIX is mediated by the human organic cation transporter, OCT2. Co-administration with inhibitors of OCT2 does not require a dose adjustment of CHAMPIX as the increase in systemic exposure to varenicline is not expected to be clinically meaningful (see cimetidine interaction below). Furthermore since metabolism of CHAMPIX represents less than 10 % of its clearance, medicines known to affect the cytochrome P450 system are unlikely to alter the pharmacokinetics of CHAMPIX (see section 5.2) and therefore a dose adjustment of CHAMPIX would not be required.

Metformin

CHAMPIX (1 mg twice daily) did not affect the pharmacokinetics of metformin (500 mg twice daily), which is a substrate of the organic cation transporter, OCT2. Metformin had no effect on CHAMPIX pharmacokinetics.

Cimetidine

Co-administration of an OCT2 inhibitor, cimetidine (300 mg four times daily), with CHAMPIX (2 mg single dose) increased the systemic exposure of CHAMPIX by 29 % due to a reduction in CHAMPIX renal clearance. No dosage adjustment is recommended based on concomitant cimetidine administration.

Digoxin

CHAMPIX (1 mg twice daily) did not alter the steady-state pharmacokinetics of digoxin administered as a 0,25 mg daily dose.

Warfarin

CHAMPIX (1 mg twice daily) did not alter the pharmacokinetics of a single 25 mg dose of (R, S)-warfarin. Prothrombin time (INR) was not affected by CHAMPIX. Smoking cessation itself may result in changes to warfarin pharmacokinetics. However, in post-marketing data there were cases of increased INR. INR should be monitored more frequently, and the warfarin dose adjusted while using CHAMPIX, and after discontinuation of CHAMPIX (see section 4.4).

Alcohol

There are limited clinical data on any potential interaction between alcohol and CHAMPIX. There have been post marketing reports of increased intoxicating effects of alcohol in patients treated with CHAMPIX. A causal relationship between these events and CHAMPIX use has not been established. Some cases described unusual and sometimes aggressive behaviour and were often accompanied by amnesia for the events. Advise patients to reduce the amount of alcohol they consume while taking CHAMPIX until they know whether CHAMPIX affects their tolerance for alcohol.

Use with other therapies for smoking cessation

Bupropion

CHAMPIX (1 mg twice daily) did not alter the steady-state pharmacokinetics of bupropion (150 mg twice daily). However, the incidence of nausea was doubled with co-administration.

Nicotine replacement therapy (NRT)

When CHAMPIX (1 mg twice daily) and NRT (transdermal 21 mg/day) were co-administered to smokers (N=24) for 12 days, there was a statistically significant decrease in average systolic blood pressure (mean 2,6 mmHg) measured on the final day of the study. In this study, the incidence of nausea, headache, vomiting, dizziness, dyspepsia, and fatigue was greater for the combination than for NRT alone.

Safety and efficacy of CHAMPIX in combination with other smoking cessation therapies have not been studied.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

Where therapy is initiated, treatment should be timed such that the course is completed before conception occurs.

Pregnancy

The safety of CHAMPIX in human pregnancy has not been established. The use of CHAMPIX in pregnant women is not recommended.

CHAMPIX was not teratogenic in rats and rabbits at oral doses up to 15 and 30 mg/kg/day, respectively (36 and 50-times the maximum recommended human daily exposure based on AUC at 1 mg BD, respectively).

Breastfeeding

The safety of CHAMPIX during lactation has not been established. Mothers on CHAMPIX should therefore not breastfeed their infants.

4.7 Effects on ability to drive and use machines

Patients should be advised to use caution driving or operating machinery until they know how quitting smoking and/or CHAMPIX may affect them.

4.8 Undesirable effects

Smoking cessation with or without treatment is associated with various symptoms. For example, dysphoric or depressed mood, insomnia, irritability, frustration or anger, anxiety, difficulty concentrating, restlessness, decreased heart rate, increased appetite or weight gain have been reported in patients attempting to stop smoking. No attempt has been made in either the design or the analysis of the CHAMPIX studies to distinguish between adverse events associated with study drug treatment or those possibly associated with nicotine withdrawal.

In patients treated with the recommended dose of 1 mg twice daily following an initial titration period the adverse event most commonly reported was nausea (28,6 %). In the majority of cases nausea occurred early in the treatment period, was mild to moderate in severity.

Tabulated summary of adverse reactions

In the table below all adverse reactions which occurred at an incidence greater than placebo are listed by system organ class and frequency: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000). The adverse reactions may also be associated with the underlying disease and/or concomitant medications.

System organ class	**Frequency**	**Adverse drug reactions**
Infections and infestations	Very common	Nasopharyngitis
	Common	Bronchitis, sinusitis
	Uncommon	Fungal infection, viral infection
Blood and lymphatic system disorders	Uncommon	Decreased platelet count
Metabolism and nutrition disorders	Common	Increased weight, decreased appetite, increased appetite
	Uncommon	Anorexia, polydipsia
Psychiatric disorders	Very common	Abnormal dreams, insomnia
	Uncommon	Panic reaction, bradyphrenia, abnormal thinking, mood swings, increased libido, decreased libido, dysphoria
Nervous system disorders	Very common	Headache
	Common	Somnolence, dizziness, dysgeusia, tremor, lethargy, hypoaesthesia, hypertonia, dysarthria, abnormal coordination

	Uncommon	Restlessness, hypogeusia, circadian rhythm sleep disorder
Cardiac disorders	Uncommon	Angina pectoris, tachycardia, palpitations, increased heart rate, atrial fibrillation, electrocardiogram ST segment depression, decreased electrocardiogram T wave amplitude
Vascular disorders	Uncommon	Increased blood pressure, hot flush
Eye disorders	Uncommon	Conjunctivitis, eye pain, scotoma, scleral discolouration, mydriasis, photophobia, myopia, increased lacrimation
Ear and labyrinth disorders	Uncommon	Tinnitus
Respiratory, thoracic and	Common	Dyspnoea, cough

mediastinal disorders	Uncommon	Upper respiratory tract inflammation, respiratory tract congestion, dysphonia, allergic rhinitis, throat irritation, sinus congestion, upper airway cough syndrome, hoarseness, rhinorrhoea, pharyngolaryngeal pain, snoring, postnasal drip
Gastrointestinal disorders	Very common	Nausea
	Common	Gastroesophageal reflux disease, vomiting, constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth, stomach discomfort
	Uncommon	Haematochezia, gastritis, change of bowel habit, eructation, aphthous stomatitis, gingival pain, haematemesis, abnormal faeces, coated tongue

Skin and subcutaneous tissue disorders	Common	Generalised rash, pruritus
	Uncommon	Erythema, acne, hyperhidrosis, night sweats
Musculoskeletal and connective tissue disorders	Common	Arthralgia, myalgia, back pain
	Uncommon	Muscle spasms, chest wall pain, joint stiffness, costochondritis
Renal and urinary disorders	Uncommon	Pollakiuria, nocturia, glycosuria, polyuria
Reproductive system and breast disorders	Uncommon	Menorrhagia, vaginal discharge, sexual dysfunction
General disorders and administration site conditions	Common	Chest pain, fatigue
	Uncommon	Chest discomfort, influenza-like illness, pyrexia, asthenia, malaise, feeling cold, cyst
Investigations	Common	Abnormal liver function test
	Uncommon	Abnormal semen analysis, increased C-reactive protein, decreased blood calcium

Post-marketing experience

The following adverse events have been reported during post-approval use of CHAMPIX. Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to medicine exposure.

There have been reports of depression, mania, psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, anxiety, and panic, as well as suicidal ideation, suicide attempt, completed suicide, mood swings, nightmares, insomnia, aggressiveness, suicidal tendency, irritability, abnormal dreaming, abnormal behaviour, psychotic reaction NOS, personality disorder, depressed mood, impaired concentration, agitation, sleepiness, emotional disorder, increased appetite, aggressive reaction, disturbed sleep, reaction, memory loss, forgetfulness, absence of appetite, anger, nervousness, mood disorder, abnormal mental state, drowsiness, confusion, abnormal thinking, sleeplessness, sleep disorder, sleep difficulty, impulsive behaviour, abnormal hunger, emotional lability, disorientation, aggravated depression, depressed state, depressed reaction, completed suicide, acute stress reaction, thoughts of self-harm, irrational thinking, suicide, marked restlessness, nervous tension, narcolepsy, mental impairment, mental disorder, memory impairment, memory disturbance, manic reaction, lethargy, lack of motivation, jitteriness, intentional self-injury, hypersomnia, auditory hallucination, flat effect, feeling strange, feeling high, feeling detached, euphoria, dissociative disorder, delirium, character change, bipolar disorder, loss of appetite, impaired appetite, decreased appetite, apathy, anti-social behaviour and acute stress disorder in patients attempting to quit smoking while taking CHAMPIX (see section 4.4).

Smoking cessation with or without treatment is associated with nicotine withdrawal symptoms and the exacerbation of underlying psychiatric illness. Not all patients had known pre-existing psychiatric illness and not all had discontinued smoking.

There have been reports of hypersensitivity reactions, including angioedema. Clinical signs included swelling of the face, mouth (tongue, lips, and gums), extremities, and neck (throat and larynx) (see section 4.4).

There have also been reports of serious skin reactions, including Stevens Johnson Syndrome and Erythema

Multiforme in patients taking CHAMPIX (see section 4.4).

There have been reports of seizures, feeling abnormal and crying.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

No cases of overdose were reported in pre-marketing clinical trials.

In case of overdose, standard supportive measures should be instituted as required.

CHAMPIX has been shown to be dialysed in patients with end stage renal disease (see section 5.2), however, there is no experience in dialysis following overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 34 Other

Varenicline binds at the α4β2 neuronal nicotinic acetylcholine receptors, where it acts as a partial agonist – a compound that has both agonist and antagonist activities, with lower intrinsic efficacy than nicotine, and antagonist activities in the presence of nicotine.

Electrophysiology studies *in vitro* and neurochemical studies *in vivo* have shown that varenicline binds to the α4β2 neuronal nicotinic acetylcholine receptors and stimulates receptor-mediated activity, but at a significantly lower level than nicotine. Nicotine competes for the same human α4β2 nAChR binding site for which

varenicline has higher affinity. Therefore, varenicline can effectively block the ability of nicotine to activate the α4β2 receptor and the mesolimbic dopamine system, the neuronal mechanism underlying reinforcement and reward experienced upon smoking. Varenicline is highly selective and binds more potently to the α4β2 receptor subtype (Ki=0.15 nM) than to other common nicotinic receptors (> 500-fold α3β4, > 3 500-fold α7, > 20 000-fold α1βγδ), (α3β4 Ki=84 nM, α7 Ki=620 nM, α1βγδ Ki=3,400 nM), or to non-nicotinic receptors and transporters (> 2 000-fold), (Ki > 1μM, except to 5-HT3 receptors: Ki=350 nM).

Clinical efficacy

The efficacy of CHAMPIX in smoking cessation was demonstrated in 3 clinical trials involving chronic cigarette smokers (≥ 10 cigarettes per day). Two thousand six hundred nineteen (2619) patients received CHAMPIX 1 mg twice a day (titrated during the first week), 669 patients received bupropion 150 mg twice a day (also titrated) and 684 patients received placebo.

5.2 Pharmacokinetic properties

Absorption

Maximum plasma concentrations of varenicline occur typically within 3 – 4 hours after oral administration. Following administration of multiple oral doses to healthy volunteers, steady-state conditions were reached within 4 days.

Absorption is virtually complete after oral administration and systemic availability is high.

Oral bioavailability of varenicline is unaffected by food or time-of-day dosing.

Distribution

Varenicline distributes into tissues, including the brain. Apparent volume of distribution averaged 415 L (% CV= 50) at steady state. Plasma protein binding of varenicline is low (≤ 20 %) and independent of both age and renal function.

Biotransformation

Varenicline undergoes minimal metabolism with 92 % excreted unchanged in the urine and less than 10 % excreted as metabolites. Minor metabolites in urine include varenicline N-carbamoylglucuronide and hydroxyvarenicline. In circulation, varenicline comprises 91 % of medicine-related material. Minor circulating metabolites include varenicline N-carbamoylglucuronide and N-glucosylvarenicline.

Elimination

The elimination half-life of varenicline is approximately 24 hours. Renal elimination of varenicline is primarily through glomerular filtration along with active tubular secretion via the organic cationic transporter, OCT2 (see section 4.5).

Linearity/Non-linearity

Varenicline exhibits linear kinetics when given as single (0,1 to 3 mg) or repeated 1 to 3 mg/day doses.

Pharmacokinetics in special patient populations

There are no clinically meaningful differences in varenicline pharmacokinetics due to age, race, gender, smoking status, or use of concomitant medicines, as demonstrated in specific pharmacokinetic studies and in population pharmacokinetic analyses.

Hepatic impairment

Due to the absence of significant hepatic metabolism, varenicline pharmacokinetics should be unaffected in patients with hepatic impairment (see section 4.2).

Renal insufficiency

Varenicline pharmacokinetics were unchanged in subjects with mild renal impairment (estimated creatinine clearance > 50 mL/min and ≤ 80 mL/min). In patients with moderate renal impairment (estimated creatinine clearance ≥ 30 mL/min and ≤ 50 mL/min), varenicline exposure increased 1,5-fold compared with subjects with normal renal function (estimated creatinine clearance > 80 mL/min). In subjects with severe renal impairment (estimated creatinine clearance < 30 mL/min), varenicline exposure was increased 2,1-fold. In subjects with end-stage-renal disease (ESRD), varenicline was removed by haemodialysis. No dosing

adjustment is necessary for patients with mild to moderate renal impairment and a reduced dosing frequency of 1 mg once daily is recommended for patients with severe renal impairment (see section 4.2). Dosing should begin at 0,5 mg once daily for the first 3 days, and then increased to 1 mg once daily.

Elderly

No dosage adjustment is necessary for elderly patients (see section 4.2). A combined single and multiple-dose pharmacokinetic study demonstrated that the pharmacokinetics of 1 mg varenicline given once or twice daily to 16 healthy elderly male and female smokers (aged 65 – 75 yrs) for 7 consecutive days was similar to that of younger subjects. For elderly patients with reduced renal function please refer to section 4.2.

Paediatric population

Because the safety and effectiveness of varenicline in paediatric patients have not been established, varenicline is not recommended for use in patients under 18 years of age (see section 4.2).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Calcium hydrogen phosphate anhydrous

Croscarmellose sodium

Magnesium stearate

Microcrystalline cellulose

Colloidal anhydrous silica

Film coating

Glycerol triacetate

Hypromellose

Indigo carmine aluminium lake E132

Macrogols

Titanium dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at room temperature, at or below 25 °C.

6.5 Nature and contents of container

Starter (initial dosing) pack containing 2 clear Aclar-PVC/Aluminium or PVC/Aluminium blisters: one blister of 11 x CHAMPIX 0,5 mg film-coated tablets and one blister of 14 x CHAMPIX 1 mg film-coated tablets in a carton.

Starter (initial dosing) pack containing 4 clear Aclar-PVC/Aluminium or PVC/Aluminium blisters: one blister of 11 x CHAMPIX 0,5 mg film-coated tablets and three blisters of 14 x CHAMPIX 1 mg film-coated tablets in a carton.

Follow-on (maintenance) pack containing 2 or 4 clear Aclar-PVC/Aluminium or PVC/Aluminium blisters of 14 x CHAMPIX 1 mg film-coated tablets in a carton.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

8. REGISTRATION NUMBERS

CHAMPIX 0,5 mg film-coated tablets: 41/34/0573

CHAMPIX 1 mg film-coated tablets: 41/34/0574

9. DATE OF FIRST AUTHORISATION

26 November 2010

10. DATE OF REVISION OF THE TEXT

10 February 2021

Manufacturer: R-Pharm Germany GmbH, Illertissen, Germany

BOTSWANA: S2

CHAMPIX 0,5 mg: Reg. No.: BOT1202097

CHAMPIX 1,0 mg: Reg. No.: BOT1202098

NAMIBIA: S2

CHAMPIX 0,5 mg: Reg. No.: 12/34/0096

CHAMPIX 1,0 mg: Reg. No.: 12/34/0097

ZIMBABWE: PP

CHAMPIX 0,5 and 1 mg: Reg. No.: 2014/6.3.2/4853