PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

CHAMPIX® 0,5 mg Film-coated tablets

CHAMPIX® 1 mg Film-coated tablets

Varenicline tartrate

Sugar free

Read all of this leaflet carefully before you start taking CHAMPIX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CHAMPIX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CHAMPIX is and what it is used for
2. What you need to know before you take CHAMPIX
3. How to take CHAMPIX
4. Possible side effects
5. How to store CHAMPIX
6. Contents of the pack and other information

1. What CHAMPIX is and what it is used for

CHAMPIX is a medicine used to help you stop smoking, in addition to a behavioural modification programme.

CHAMPIX can help to relieve the craving and withdrawal symptoms associated with stopping smoking.

It is recommended that you do not smoke while taking CHAMPIX.

2. What you need to know before you take CHAMPIX

Do not take CHAMPIX:

If you are hypersensitive (allergic) to varenicline or to any of the other ingredients of CHAMPIX (listed in section 6).

Warnings and precautions

Take special care with CHAMPIX:

- tell your doctor if you have kidney problems. Your doctor may prescribe a lower dose of CHAMPIX for you.
- if you have experienced depression or other mental health problems (e.g. schizophrenia, bipolar disorder). There have been reports of depression, suicidal ideation and behaviour and suicide attempts in patients taking CHAMPIX. If you are taking CHAMPIX and develop agitation, depressed mood, changes in behaviour that are of concern to you or your family or if you develop suicidal thoughts or behaviours you should stop taking CHAMPIX and contact your doctor immediately for treatment assessment.
- if you have a history of seizures (fits). Some people have reported seizures while taking CHAMPIX.
- if you experience any of the following signs and symptoms that may indicate a serious allergic reaction: swelling of the face, lips, tongue, gums, throat or body and/or difficulty breathing, wheezing. Stop taking CHAMPIX and tell your doctor immediately.
- if you develop a rash or if your skin starts to peel or blister you should stop taking CHAMPIX and seek emergency medical help. Potentially life-threatening skin rashes (Stevens-Johnson syndrome and Erythema Multiforme) have been reported with the use of CHAMPIX.
- if you have an existing heart condition, tell your doctor. New or worse heart or blood vessel (cardiovascular) problems have been reported primarily in people who already have cardiovascular problems. Tell your doctor if you have any changes in symptoms during treatment with CHAMPIX. Get emergency medical help right away if you have symptoms of a heart attack or stroke.
- tell your doctor if you are pregnant or plan to become pregnant. CHAMPIX has not been studied in pregnant women. It is not known if CHAMPIX will harm your unborn baby. It is best to stop smoking before you get pregnant.

- tell your doctor if you are breastfeeding. Although it was not studied in humans, CHAMPIX may pass into breastmilk.

The effects of stopping smoking

The effects of changes in your body resulting from stopping smoking, with or without treatment with CHAMPIX, may alter the way other medicines work. Therefore, in some cases an adjustment of the dose may be necessary. Examples include theophylline (a medicine to treat breathing problems), warfarin (a medicine to reduce blood clotting), and insulin (and other antidiabetic medicines to treat diabetes). If in doubt, you should consult your doctor or pharmacist.

For some people stopping smoking, with or without treatment, has been associated with an increased risk of experiencing changes in thinking and behaviour, feelings of depression and anxiety and can be associated with a worsening of psychiatric disorder. Patients with serious psychiatric disorder such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the clinical studies of CHAMPIX and the safety and efficacy of CHAMPIX in such patients has not been established. If you have a history of psychiatric disorder, you should discuss this with your doctor or pharmacist.

Depressed mood may appear during smoking cessation with or without treatment. Depression, rarely including suicidal thoughts and suicide attempt, has been reported in patients undergoing a smoking cessation attempt. These feelings have also been reported while attempting to quit smoking with CHAMPIX. You may temporarily experience increased irritability, urge to smoke, depression and/or sleep disturbances when you stop taking CHAMPIX. Your doctor may decide to gradually lower your dose of CHAMPIX at the end of treatment.

Other medicines and CHAMPIX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you take:

- asthma medicines (e.g. theophylline)

- insulin or other antidiabetic medicines
- blood-thinning medicines (e.g. warfarin)
- gastrointestinal medicines (e.g. cimetidine)

Use of CHAMPIX with other therapies for smoking cessation

The safety and benefits of taking CHAMPIX in combination with other medicines for stopping smoking have not been studied. CHAMPIX in combination with any other smoking cessation therapies is therefore not recommended.

CHAMPIX with food, drink and alcohol

CHAMPIX may be taken at any time before or after meals.

Increased intoxicating effects of alcohol in patients treated with CHAMPIX have been reported. Some cases described unusual and sometimes aggressive behaviour and were often accompanied by amnesia for the events. You should reduce the amount of alcohol consumed while taking CHAMPIX until it is known whether it affects your tolerance for alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

CHAMPIX has not been studied in pregnant women. It is not known if CHAMPIX will harm your unborn baby. It is best to stop smoking before you get pregnant.

You should not take CHAMPIX while you are pregnant.

If you are pregnant or are planning to become pregnant, you should try to stop smoking. Stopping smoking has benefits for both you and the health of your baby. Talk to your doctor if you are intending to become

pregnant. If you want to start treatment with CHAMPIX, your treatment should be timed so that you have completed the course before becoming pregnant.

Although it was not studied in humans, CHAMPIX may pass into breastmilk.

Women taking CHAMPIX should not breastfeed their infants.

Driving and using machines

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

It is not always possible to predict to what extent CHAMPIX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CHAMPIX affects them.

3. How to take CHAMPIX

Do not share medicines prescribed for you with any other person.

You are only likely to stop smoking if you are motivated to stop and are provided with additional advice and support from a behavioural modification programme. Your doctor and pharmacist can provide advice, support and sources of further information to help ensure your attempt to stop smoking is successful.

Always take CHAMPIX exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

Choose the date to stop smoking. Start taking CHAMPIX 1 - 2 weeks before this date. You can keep smoking during this time.

You should be treated with CHAMPIX for 12 weeks.

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

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

If you do not stop smoking during the first 12 weeks of treatment or if you start smoking again after treatment, you can make another attempt at stopping smoking. However, before you make another attempt, you should try to understand the reasons why your attempt to stop smoking failed, so that your next attempt has a better chance of success.

If you are not able or willing to quit smoking straight away, you should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period. You should then continue to take CHAMPIX for a further 12 weeks resulting in a total of 24 weeks of treatment.

If you have the impression that the effect of CHAMPIX is too strong or too weak for you, tell your doctor or pharmacist.

If you have problems with your kidneys, you should speak to your doctor before taking CHAMPIX.

CHAMPIX is not recommended for use in children under 18 years.

If you take more CHAMPIX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take your box of tablets with you.

If you forget to take CHAMPIX

Do not take a double dose to make up for a forgotten individual doses. It is important that you take CHAMPIX regularly at the same time each day. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the tablet that you have missed.

If you stop taking CHAMPIX

It has been shown in clinical trials that taking all doses of your medicine at the appropriate times and for the recommended duration of treatment described above will increase your chances of stopping smoking. Therefore, unless your doctor instructs you to stop treatment, it is important to keep taking CHAMPIX, according to the instructions described in the table above, until you have completed your course of CHAMPIX.

In smoking cessation therapy, risk of returning to smoking may be elevated in the period immediately following the end of treatment. You may temporarily experience increased irritability, urge to smoke, depression and/or sleep disturbances when you stop taking CHAMPIX.

If you have any further questions on the use of CHAMPIX, ask your doctor or pharmacist.

4. Possible side effects

CHAMPIX can have side effects.

Not all side effects reported for CHAMPIX are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking CHAMPIX, please consult your health care provider for advice.

Tell your doctor if you experience any new or worsening heart or blood vessels symptoms. Seek immediate medical attention if you experience signs and symptoms of a heart attack or stroke (chest discomfort or pain, shortness of breath, dizziness, nausea, headache, difficulty with speech).

Tell your doctor if you experience agitation, depressed mood, anxiety or panic attacks, aggressive behaviour, crying, abnormal thoughts, hallucinations (seeing or hearing things that are not there), feeling confused, unusual changes in behaviour/mood, hypersensitivity reactions such as angioedema (blistering of the skin) and facial swelling, or suicidal thoughts. These symptoms have been reported in patients trying to stop smoking with or without CHAMPIX.

Tell your doctor if you notice any of the following:

Frequent side effects

- inflammation of the nasal passages and sinuses
- abnormal dreams
- difficulty sleeping
- headache
- nausea
- inflammation of the air passages (bronchitis)
- inflammation of the sinuses
- increased weight
- loss of appetite
- increased appetite
- sleepiness
- dizziness
- changes in the way things taste
- tremors
- lack of energy
- tight muscles
- slurred speech
- abnormal coordination
- difficulty breathing
- cough
- heartburn

- vomiting
- constipation
- diarrhoea
- feeling bloated
- abdominal pain
- toothache
- indigestion
- flatulence
- dry mouth
- stomach discomfort
- joint ache
- muscle ache
- skin rash
- itching
- joint pain
- muscle pain
- back pain
- chest pain
- tiredness
- abnormal liver laboratory tests

Less frequent side effects

- fungal infection
- viral infection
- decreased blood cell count
- loss of appetite
- feeling thirsty
- feeling of panic
- difficulty thinking

- mood swings
- changes in sex drive
- general uneasy feeling
- restlessness
- reduced sense of taste
- changes in sleep patterns
- chest pain
- palpitations
- increased heart rate
- abnormal heart rhythm
- abnormal electrocardiogram
- increased blood pressure
- hot flushes
- inflammation of the eye
- eye pain
- disturbed vision
- eyeball discolouration
- dilated pupils
- sensitivity to light
- short-sightedness
- watery eyes
- ringing in the ears
- inflammation of nose, sinuses and throat
- congestion
- difficulty in speaking
- runny nose
- throat irritation
- congested sinuses

- hoarseness
- throat pain
- snoring
- postnasal drip
- red blood in stools
- irritated stomach
- change in bowel habits
- burping
- mouth ulcers
- pain in the gums
- blood in vomit
- abnormal stools
- coated tongue
- reddening of the skin
- acne
- increased sweating
- sweating at night
- muscle spasms
- chest wall and rib pain
- stiff joints
- inflammation of the cartilage in the rib cage
- frequent daytime urination (passing water)
- increased urination at night
- glucose in urine
- increased urine volume
- increased menstrual flow
- vaginal discharge
- changes in sexual function

- chest discomfort
- flu-like illness
- fever
- feeling weak or unwell
- feeling cold
- cysts
- abnormal semen
- increased liver protein levels
- decreased blood calcium levels

Other side effects

Depression, mood swings, suicide ideation, nightmares, hallucinations, anxiety, aggressiveness, suicidal tendency, irritability, abnormal dreaming, abnormal behaviour, psychotic reaction NOS, personality disorder, depressed mood, impaired concentration, emotional disorder, aggressive reaction, disturbed sleep, memory loss, suicide attempt, forgetfulness, anger, paranoid reaction, nervousness, mood disorder, abnormal mental state, drowsiness, delusion, confusion, abnormal thinking, impulsive behaviour, emotional lability, disorientation, aggravated depression, depressed state, depressed reaction, completed suicide, acute stress reaction, thoughts of self-harm, irrational thinking, suicide, marked restlessness, psychosis, nervous tension, narcolepsy, mental impairment, mental disorder, memory impairment, memory disturbance, manic reaction, mania lethargy, lack of motivation, jitteriness, intentional self-injury, hypersomnia, auditory hallucination, feeling high, euphoria, dissociative disorder, delirium, character change, bipolar disorder, apathy, antisocial behaviour and acute stress disorder.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects 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. By reporting side effects, you can help provide more information on the safety of CHAMPIX.

5. How to store CHAMPIX

- Store all medicines out of reach of children.
- CHAMPIX should be kept at room temperature (at or below 25 °C).
- Do not use CHAMPIX after the expiry date that is stated on the label/carton. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CHAMPIX contains

The active substance is varenicline (as tartrate).

The other ingredients are calcium hydrogen phosphate anhydrous, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, silica, colloidal anhydrous.

Film coating: glycerol triacetate, hypromellose, indigo carmine aluminium lake E132, macrogols, titanium dioxide.

What CHAMPIX looks like and contents of the pack

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.

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.

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)

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