

PART III: CONSUMER INFORMATION
Pr CHAMPIX®
(varenicline tartrate tablets)

Read this information each time you refill your prescription in case new information has been added.

This leaflet is part III of a three-part "Product Monograph" published when CHAMPIX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CHAMPIX. Contact your doctor or pharmacist if you have any questions about the drug.

What is the most important information I should know about CHAMPIX?

When you try to quit smoking, with or without CHAMPIX, you may have symptoms that may be due to nicotine withdrawal, including

- the urge to smoke
- depressed mood
- trouble sleeping
- irritability
- frustration
- anger
- feeling anxious
- difficulty concentrating
- restlessness
- decreased heart rate
- increased appetite or weight gain.

Some people have even experienced suicidal thoughts when trying to quit smoking without medication. Sometimes quitting smoking can lead to worsening of mental health problems that you already have, such as depression.

Mental Health Problems

Some people have had serious side effects while taking CHAMPIX to help them quit smoking, including changes in behavior or thinking, hostility, agitation, aggression, depressed mood, or suicidal thoughts or actions. These symptoms have occurred in people with previous mental health problems, as well as in those with no previous history. For some people, these symptoms began when they started taking CHAMPIX while for others, they began after several weeks of treatment, or shortly after stopping CHAMPIX.

Before taking any quit-smoking treatment, including CHAMPIX, tell your healthcare provider (doctor, pharmacist or nurse):

- if you have ever had depression or other mental health problems;
- about any concerning symptoms you had during other times you tried to quit smoking, with or without medication.

Inform your friends and family members of your quit attempt with CHAMPIX and ask for their support and help in monitoring for any changes in behavior or thinking that are not normal.

Drinking alcohol may increase the risk of having mental health problems during your treatment with CHAMPIX.

Patients with history of mental health problems (eg depression, anxiety, schizophrenia): If you have had mental health problems before taking CHAMPIX, your healthcare provider will monitor you while you try to quit smoking with CHAMPIX. If you develop worsened or new symptoms, talk to your healthcare provider right away because changing the dose (of CHAMPIX or other medications) may make a difference.

All patients/General: If you have thoughts, moods or behaviours that are severe, concerning or very abnormal for you, stop taking CHAMPIX right away, seek medical help, and tell your healthcare provider about your symptoms. In many people, these symptoms went away after stopping CHAMPIX, but not in all. It is important for you to follow up with your healthcare provider until your symptoms go away.

Allergic Reactions

Some people can have allergic reactions to CHAMPIX. Some of these allergic reactions can be life-threatening and include: swelling of the face, mouth, and throat that can cause trouble breathing. If you have these symptoms, stop taking CHAMPIX and seek immediate emergency medical attention.

Serious Skin Reactions

Some people can have serious skin reactions while taking CHAMPIX. These can include rash, swelling, redness, and peeling of the skin. Some of these reactions can become life-threatening. If you have a rash with peeling skin or blisters in your mouth, around the eyes or genitals, stop taking CHAMPIX and seek immediate emergency medical attention.

ABOUT THIS MEDICATION**What the medication is used for:**

CHAMPIX is a prescription medicine which is used in combination with supportive counselling to help motivated adults stop smoking.

What it does:

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

CHAMPIX does not contain nicotine, but it has been shown to affect the nicotine receptor in the brain that is thought to be most related to smoking addiction. CHAMPIX can affect this receptor in two opposite ways: it acts like a weaker version of nicotine, and also blocks nicotine from getting to the receptor because it binds more tightly. Although it is thought that this may be, in part, how CHAMPIX works, it is not known exactly how the drug works in people.

When it should not be used:**Do not take CHAMPIX if you:**

- are allergic (hypersensitive) to varenicline tartrate or any of the other ingredients of CHAMPIX (see list below of non-medical ingredients).
- are using nicotine replacement therapy, such as patches, gum or inhaler. The combination of CHAMPIX and nicotine replacement therapy is not expected to improve your chances of quitting, and may result in more side effects than with CHAMPIX alone.

What the medicinal ingredient is:

Varenicline tartrate.

What the nonmedicinal ingredients are:

The nonmedicinal ingredients are microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, colloidal silicon dioxide and magnesium stearate. The film-coating contains hypromellose, titanium dioxide, polyethylene glycol and triacetin. The 1 mg tablet also contains FD&C Blue #2/Indigo Carmine Aluminum Lake as a colouring agent.

What dosage forms it comes in:

CHAMPIX is available as film-coated tablets. The 0.5 mg tablets are white and the 1 mg tablets are light blue.

WARNINGS AND PRECAUTIONS**BEFORE you use CHAMPIX talk to your healthcare provider if you:**

- have experienced depression or any other mental health problems. Your healthcare provider will monitor you for new or worsened emotional or behavioral problems during treatment with CHAMPIX.
- have any problems with your kidneys, as you may need a lower dose of CHAMPIX.
- have heart or blood vessel (cardiovascular) problems.
- have a history of seizures.
- have any other medical conditions.
- are pregnant, are breastfeeding or plan to become pregnant (see “Pregnancy” and “Breastfeeding” below).
- have diabetes. CHAMPIX can potentially affect your blood sugar regulation, and you may need to monitor your blood sugar more often. If you notice changes, discuss this with your healthcare provider.

The effects of changes in your body resulting from stopping smoking, with or without treatment with CHAMPIX, may alter the way other drugs work. Tell your healthcare provider about all your other medicines, including prescription and nonprescription medicines, vitamins and herbal supplements. Especially, tell your healthcare provider if you take:

- o Insulin
- o Asthma medicines (theophylline)
- o Blood thinner (warfarin)

as an adjustment of the dose of these medicines may be necessary once you are smoke-free.

Mental Health Symptoms

See “What is the most important information I should know about CHAMPIX?”

Pregnancy

Talk to your healthcare provider if you are pregnant or planning to become pregnant.

You should not take CHAMPIX while you are pregnant. It is unknown if CHAMPIX will harm your unborn baby.

It is best to stop smoking before you get pregnant.

Breastfeeding

You should ask your healthcare provider for advice before taking any medication, including CHAMPIX, if you are breastfeeding, as the medicine may pass into breast milk.

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

Accidental Injury, including while Driving, Operating Machinery

Do not engage in potentially hazardous tasks, such as driving a car or operating dangerous machines, until you know how CHAMPIX may affect you. In some cases, people have reported sleepiness, dizziness, blackouts, seizures or difficulty concentrating while driving.

Seizures

Tell your healthcare provider if you have experienced seizures or have epilepsy before you start CHAMPIX treatment. Some people have reported seizures while taking CHAMPIX, both with and without a history of seizures.

Heart or Stroke Events

New or worse heart or blood vessel (cardiovascular) problems have been reported in people taking CHAMPIX, primarily in those who already have cardiovascular problems. From the information available to date, it is not possible to determine whether CHAMPIX increases the risk of heart or stroke events.

Tell your healthcare provider if you have any changes in cardiovascular symptoms during treatment with CHAMPIX. Get emergency medical help right away if you have symptoms of a heart attack, including any of the following:

- Chest discomfort (uncomfortable pressure, squeezing, fullness or pain) that lasts more than a few minutes, or that goes away and comes back.
- Pain or discomfort in one or both arms, back, neck, jaw or stomach.
- Shortness of breath, sweating, nausea, vomiting, or feeling lightheaded associated with chest discomfort.

Get emergency medical help right away if you have symptoms of a stroke, including any of the following:

- Weakness - Sudden loss of strength or sudden numbness in the face, arm or leg even if temporary.
- Trouble speaking - Sudden difficulty speaking or understanding or sudden confusion, even if temporary.
- Vision problems - Sudden trouble with vision, even if temporary.

- Headache - Sudden severe and unusual headache.
- Dizziness - Sudden loss of balance, especially with any of the above signs.

Sleepwalking

Sleepwalking has been reported in patients taking CHAMPIX, and may sometimes lead to behaviour that is harmful to you or other people or property. Stop taking CHAMPIX and tell your healthcare provider if you start sleepwalking.

INTERACTIONS WITH THIS MEDICATION

Drinking alcohol during treatment with CHAMPIX may increase the risk of mental health symptoms.

Reported experiences include:

- **unusual or sometimes aggressive behavior;**
- **more intoxicated than expected from the amount of alcohol;**
- **no memory of things that have happened.**

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. Taking CHAMPIX in combination with other smoking-cessation therapies (eg, nicotine replacement therapy) is therefore not recommended. Using CHAMPIX in combination with nicotine replacement therapies (eg, patch gum or inhaler) is not likely to increase your chances of quitting smoking, and it may result in more side effects than with CHAMPIX alone.

PROPER USE OF THIS MEDICATION

You are more likely to stop smoking if you are motivated to stop. Your healthcare provider can provide advice, support and sources of further information to help ensure your attempt to stop smoking is successful.

To increase the chances of success, CHAMPIX should be used in combination with supportive counselling as recommended by your healthcare provider. CHAMPIX was used in combination with supportive counselling in the clinical trials. At any time, you can also call government-funded toll-free provincial Quit Lines, to speak to a knowledgeable and supportive specialist; these phone numbers are available on the Health Canada website, or by calling 1-800-CHAMPIX.

Always take CHAMPIX exactly as your healthcare provider has told you. You should check with your healthcare provider if you are not sure.

REMEMBER: This medication has been prescribed specifically for you. Do not give it to anyone else.

Setting Your Quit Date:

Starting treatment before your quit date lets CHAMPIX build up in your body. You can keep smoking until your quit date.

There are three ways to set your quit date when using CHAMPIX. Talk to your healthcare provider about which way is best for you:

- Fixed quit approach: Set a quit date when you will stop smoking. Start taking CHAMPIX 8 - 14 days (1 to 2 weeks) before your quit date. You should take CHAMPIX for 12 weeks. After 12 weeks of treatment, your healthcare provider may recommend an additional 12 weeks of treatment.

Or

- Flexible quit approach: Start taking CHAMPIX, then quit smoking between Day 8 and Day 35 after the start of your treatment (ie between Weeks 2 and 5). You should take CHAMPIX for 12 weeks. After 12 weeks of treatment, your healthcare provider may recommend an additional 12 weeks of treatment.

Or

- Gradual quit approach: Start taking CHAMPIX and reduce smoking with a goal to quit smoking by end of 12 weeks of treatment. For example, reduce smoking by half by the 4th week, another half by the 8th week (down to 25%) and then quit by the end of the 12th week. You may quit any time before the end of 12 weeks of treatment, if you are able to. Continue treatment for an additional 12 weeks for a total of 24 weeks.

Write down, and keep in a visible or convenient place (for example on the fridge or on the CHAMPIX pack), the date that you started CHAMPIX, your quit date, and the date to stop taking CHAMPIX.

Make sure that you try to stop smoking on your quit date. If you slip-up and smoke after that target date, keep trying. Some people need a few weeks on CHAMPIX for it to work best.

Dosing Options:

CHAMPIX should be taken after eating and with a full glass of water.

Regardless of which dose is prescribed, the first week on CHAMPIX is the same, and is described in the following table:

Week 1 Dosing Schedule:

Day	Dose
Day 1 – 3	Take one white CHAMPIX 0.5 mg tablet once a day.
Day 4 - 7	Take one white CHAMPIX 0.5 mg tablet twice a day, once in the morning and once in the evening, at about the same time each day.

After the first week, your healthcare provider may recommend to stay at 0.5 mg twice a day (**OPTION 1**) or go up to 1 mg twice a day (**OPTION 2**).

Week 2 (day 8) to the end of treatment

OPTION 1: Continue on 0.5 mg twice a day

Day	Dose
Day 8- end of treatment	0.5 mg twice a day: Continue to take one white CHAMPIX 0.5 mg pill in the morning, and one in the evening, at about the same time each day

Or

OPTION 2: Start taking 1 mg twice a day

Day	Dose
Day 8- end of treatment	1 mg twice a day: Take one light blue CHAMPIX 1 mg pill in the morning, and one in the evening, at about the same time each day

The maximum dose of CHAMPIX is 1 mg twice a day.

Based on the limited data available, the two doses do not appear different in terms of either quit rates, or rates of

serious mental health side effects (your healthcare provider can provide more information).

Discussion with your healthcare provider is important in order to choose the dose that is best for you.

If needed, the dose can be changed depending on how well you tolerate CHAMPIX and how effective your healthcare provider and you consider it is in helping you quit smoking. Your healthcare provider will help decide what dose is right for you.

Your healthcare provider may recommend to gradually lower the dose at the end of the treatment period rather than stopping abruptly.

Can I smoke while taking CHAMPIX?

You can keep smoking prior to your quit date.

Smoking after your quit date will reduce your chance of breaking your smoking addiction.

Some people have reported a change in the taste of cigarettes after starting CHAMPIX.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Do not take a double dose to make up for a forgotten tablet. 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, as long as it is within a few hours of the missed dose. If it is has been longer than a few hours since the missed dose, or if you do not remember whether you took a dose or not, then skip that dose, and wait to take the next dose at the correct time.

If you have any further questions on the use of this product, ask your healthcare provider.

Your appetite may increase, and you may gain some weight.

Like all medicines, CHAMPIX can cause side effects, although not everybody gets them.

The common side effects are mostly mild to moderate and these usually occur in the first weeks of treatment.

Some of the most common side effects you should be aware of include:

- Nausea, vomiting
- Trouble sleeping
- Headache
- Abnormal dreams (vivid, unusual, or increased dreaming; rarely may include nightmares)
- Sleepiness, tiredness, dizziness
- Constipation, diarrhea, gas

Mental Health Problems

See “**What is the most important information I should know about CHAMPIX?**”

Stop taking CHAMPIX if you experience severe or unusual feelings of agitation, aggression, depressed mood, hostility, hallucinations, or if you have thoughts of self-harm or harm to others. Tell your healthcare provider about your symptoms.

Allergic Reactions

Some people have allergic reactions to CHAMPIX. Some of these allergic reactions can be life-threatening and include: swelling of the face, mouth (lips, gums, tongue), and throat can cause trouble breathing. If you have these symptoms, stop taking CHAMPIX and seek immediate emergency medical attention.

Serious Skin Reactions

Some people can have serious skin reactions while taking CHAMPIX. These can include rash, swelling, redness, and peeling of the skin. Some of these reactions can become life-threatening. If you have a rash with peeling skin, or blistering of the mouth, around the eyes or genitals, stop taking CHAMPIX and seek immediate emergency medical attention.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Whether you are taking medication to stop smoking or not, the following are symptoms you may feel: depressed, short-tempered, frustrated or angry, nervous, impatient; have difficulty concentrating.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Rare	Allergic reaction redness, itching or swelling of your skin, hives, burning, stinging, swelling of the neck area, or any difficulty with breathing, not present before using this medicine			X
Rare	Serious skin reactions peeling of the skin, or rash combined with blisters around the mouth, eyes or genitals.			X
Rare	Mental Health Problems		X	X (if severe, or if involves potential for harm to self or others)
Unknown	Heart attack: chest pain often associated with left shoulder or jaw pain, feeling of constriction around chest and sweating			X

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Unknown	Stroke: weakness and/or loss of sensation of limbs or face, difficulty speaking, clumsiness, visual loss			X
Unknown	Seizures: Loss of consciousness with uncontrollable shaking (convulsion)			X
Unknown	Sleepwalking		X (and stop taking CHAMPIX)	

This is not a complete list of side effects. For any unexpected effects while taking CHAMPIX, contact your doctor or pharmacist.

HOW TO STORE IT

Store CHAMPIX at room temperature (15°C – 30°C).

Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.Pfizer.ca>
or by contacting the sponsor, Pfizer Canada Inc., at:
1-800-463-6001

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Last revised: February 20, 2017