

PART III: CONSUMER INFORMATIONPr **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.

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

CHAMPIX is a prescription medicine which is used 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 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.

To increase the chances of success, CHAMPIX should be used in combination with supportive counselling as recommended by your doctor or pharmacist.

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).
- If you 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 important nonmedicinal ingredients are:

The non-medicinal 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 doctor or pharmacist if:**

- You are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- You have any problems with your kidneys, as you may need a lower dose of CHAMPIX.

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 doctor 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.

Pregnancy

Talk to your doctor 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 doctor or pharmacist 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.

Driving and using machines

Do not engage in potentially hazardous tasks, such as driving a car or operating dangerous machines, until you are sure that this medication does not affect your mental alertness or physical coordination.

INTERACTIONS WITH THIS MEDICATION

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.

CHAMPIX may be taken with or without food.

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

Can I smoke while taking CHAMPIX?

You can keep smoking prior to your quitting date. However, before starting your course of CHAMPIX you should decide on a date in the second week of treatment (between Day 8 and Day 14) when you will stop smoking.

Continuing to smoke after your quit date will reduce your chance of breaking your smoking addiction.

Overdose:

If you accidentally take more CHAMPIX than your doctor prescribed, you must seek medical advice or go to the nearest hospital emergency department immediately. Take your medication with you.

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 longer than that 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 doctor or pharmacist.

PROPER USE OF THIS MEDICATION

You are more likely to stop smoking if you are motivated to stop. 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 has told you. You should check with your doctor or pharmacist if you are not sure.

Before starting your course of CHAMPIX you should decide on a date in the second week of treatment (between Day 8 and Day 14) when you will stop smoking. This lets CHAMPIX build up in your body. You can keep smoking during this time. You should write your quit date on the CHAMPIX pack as a reminder. If you slip after that target date, keep trying. Some people need a few weeks of CHAMPIX to work best.

Usual dose:

The usual dose for adults which you should follow from Day 1 is described in the following table:

Week 1	Dose
Days 1 - 3	Take one white CHAMPIX 0.5 mg tablet once a day.
Days 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.
Days 8 – end of treatment	Take one light blue CHAMPIX 1 mg tablet twice a day, once in the morning and once in the evening, at about the same time each day.

The maximum dose that could be prescribed to you is 2 mg/day.

If you are experiencing problematic side effects, talk with your doctor who may reduce your dose temporarily or permanently.

You should take CHAMPIX for 12 weeks.

If you have stopped smoking after 12 weeks of treatment, your doctor may recommend additional weeks of CHAMPIX treatment.

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. 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.

The most common side effects include:

- Nausea
- Vomiting
- Trouble sleeping
- Headache
- Abnormal dreams
- Constipation

- Gas

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 call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Allergic reaction such as: redness, itching or swelling of your skin, hives, burning, stinging, or any other skin problems, swelling of the neck area, or any difficulty with breathing, not present before using this medicine	X		X

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

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
 toll-free fax: 866-678-6789
 By email: cadtmp@hc-sc.gc.ca

By regular mail:
National AR Centre
Marketed Health Products Safety and Effectiveness Information Division
Marketed Health Products Directorate
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

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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HOW TO STORE IT

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

Keep out of the reach of children.

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