

MEDICATION GUIDE

CHAMPIX®

(Varenicline) Tablets

Read the Medication Guide that comes with CHAMPIX before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your condition or treatment.

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

Some people have had serious side effects while using CHAMPIX to help them quit smoking including: New or worse mental health problems, such as changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts or actions. Some people had these symptoms when they began taking CHAMPIX, and others developed them after several weeks of treatment, or after stopping CHAMPIX.

Before taking CHAMPIX, tell your doctor if you have ever had depression or other mental health problems. You should also tell your doctor about any symptoms you had during other times you tried to quit smoking, with or without CHAMPIX.

Stop taking CHAMPIX and call your doctor right away if you, your family, or caregiver notice agitation, hostility, depression or changes in your behavior or thinking that are not typical for you, or you develop any of the following symptoms:

- thoughts about suicide or dying, or attempts to commit suicide
- new or worse depression, anxiety, or panic attacks
- feeling very agitated or restless
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- abnormal thoughts or sensations

- seeing or hearing things that are not there (hallucinations)
- feeling people are against you (paranoia)
- feeling confused
- other unusual changes in behavior or mood

When you try to quit smoking, with or without CHAMPIX, you may have symptoms that may be due to nicotine withdrawal, including urge to smoke, depressed mood, trouble sleeping, irritability, frustration, anger, feeling anxious, difficulty concentrating, restlessness, decreased heart rate, and 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.

See “ **What are the possible side effects of CHAMPIX?**” for more information about other side effects.

What is CHAMPIX?

CHAMPIX is a prescription medicine to help people stop smoking.

Quitting smoking can lower your chances of having lung disease, heart disease or getting certain types of cancer that are related to smoking.

It is not known if CHAMPIX is safe and effective in children. It is not known if CHAMPIX is safe and effective when used with other stop smoking medicines.

Who should not take CHAMPIX?

Do not take CHAMPIX if you have had a serious allergic or skin reaction to CHAMPIX.

Symptoms may include:

Swelling of the face, mouth (tongue, lips, gums), throat or neck

Trouble breathing

Rash, with peeling skin

Blisters in your mouth

What should I tell my doctor before taking CHAMPIX?

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

Before you take CHAMPIX, tell your doctor if you:

- use other treatments to quit smoking. Using CHAMPIX with a nicotine patch may cause nausea, vomiting, headache, dizziness, upset stomach, and tiredness to happen more often than if you just use a nicotine patch alone.
- have kidney problems or get kidney dialysis. Your doctor may prescribe a lower dose of CHAMPIX for you.
- have a history of seizures.
- drink alcohol.
- have heart or blood vessel problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if CHAMPIX will harm your unborn baby.
- are breastfeeding. It is not known if CHAMPIX passes into breast milk. If you breastfeed and take CHAMPIX, monitor your baby for seizures as well as spitting up or vomiting more than normal.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Your doctor may need to change the dose of some of your medicines when you stop smoking.

You should not use CHAMPIX while using other medicines to quit smoking. Tell your doctor if you use other treatments to quit smoking.

Know the medicines you take. Keep a list of them with you to show your doctor and pharmacist when you get a new medicine.

How should I take CHAMPIX?

- There are 3 ways that you can use CHAMPIX to help you quit smoking. Talk to your doctor about the following 3 ways to use CHAMPIX.
 1. Choose a **quit date** when you will stop smoking. Start taking CHAMPIX 1 week (7 days) before your **quit date**. **Take CHAMPIX for 12 weeks.**

OR

2. Start taking CHAMPIX before you choose a **quit date**. Pick a date to quit smoking that is between days 8 and 35 of treatment. Take CHAMPIX for 12 weeks.

OR

3. If you are sure that you are not able or willing to quit smoking right away, start taking CHAMPIX and reduce smoking during the first 12 weeks of treatment, as follows:

Weeks 1 through 4	Reduce your smoking to reach one-half of your starting daily number of cigarettes. Example: If you usually smoke 20 cigarettes each day, reduce your smoking to 10 cigarettes each day during weeks 1 through 4.
Weeks 5 through 8	Reduce your smoking to reach one-quarter of your starting daily number of cigarettes. Example: If you usually smoked 20 cigarettes each day, reduce your smoking to 5 cigarettes each day during weeks 5 through 8.
Weeks 9 through 12	Keep reducing your smoking until you are no longer smoking (you reach zero cigarettes each day).

Aim to quit by the end of the 12th week of treatment, or sooner if you feel ready. Continue to take CHAMPIX for another 12 weeks, for a total of 24 weeks of treatment.

Starting CHAMPIX before your quit date gives CHAMPIX time to build up in your body. You can keep smoking during this time. Take CHAMPIX exactly as prescribed by your doctor.

1. Make sure that you try to stop smoking on your quit date. If you slip-up and smoke, try again. Some people need to take CHAMPIX for a few weeks for CHAMPIX to work best.
2. Most people will take CHAMPIX for up to 12 weeks. If you completely quit smoking by 12 weeks, your doctor may prescribe CHAMPIX for another 12 weeks to help you stay cigarette-free.
3. Take CHAMPIX with a full glass (8 ounces) of water.
4. This dosing schedule may not be right for everyone. Talk to your doctor if you are having side effects such as nausea, strange dream, or sleep problems. Your doctor may want to reduce your dose.
5. If you miss a dose of CHAMPIX, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Just take your next dose at your regular time. CHAMPIX comes as a white tablet (0.5 mg) and a blue tablet (1 mg). You start with the white tablet and then usually go to the blue tablet. See the chart below for dosing instructions.

<u>Day 1 to Day 3</u>	<ul style="list-style-type: none">• <u>White</u> tablet (0.5 mg)• Take 1 tablet each day
<u>Day 4 to Day 7</u>	<ul style="list-style-type: none">• <u>White</u> tablet (0.5 mg)• Take 1 in the morning and 1 in the evening
<u>Day 8 to end of treatment</u>	<ul style="list-style-type: none">• <u>Blue</u> tablet (1 mg)• Take 1 in the morning and 1 in the evening

What should I avoid while taking CHAMPIX?

Use caution when driving or operating machinery until you know how CHAMPIX affects you. CHAMPIX may make you feel sleepy, dizzy, or have trouble concentrating, making it hard to drive or perform other activities safely.

- Decrease the amount of alcoholic beverages that you drink during treatment with CHAMPIX until you know if CHAMPIX affects your ability to tolerate alcohol. Some people have experienced the following when drinking alcohol during treatment with CHAMPIX:

- increased drunkenness (intoxication)
- unusual or sometimes aggressive behavior
- no memory of things that have happened

What are the possible side effects of CHAMPIX?

Serious side effects of CHAMPIX may include:

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

Seizures. Some people have had seizures during treatment with CHAMPIX. In most cases, the seizures have happened during the first month of treatment with CHAMPIX. If you have seizure during treatment with CHAMPIX, stop taking CHAMPIX and contact your doctor right away.

- **New or worse heart or blood vessel (cardiovascular) problems**, mostly 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 any of the following symptoms of a heart attack, including:

- 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
- Sleepwalking can happen with CHAMPIX, and can sometimes lead to behavior that is harmful to you or other people, or to property. Stop taking CHAMPIX and

tell your doctor if you start sleep walking.

- Allergic reactions can happen with CHAMPIX. Some of these allergic reactions can be life-threatening.
- Serious skin reactions, including rash, swelling, redness, and peeling of the skin. Some of these skin reactions can become life-threatening.
- Stop taking CHAMPIX and get medical help right away if you have any of the following symptoms:

Swelling of the face, mouth (tongue, lips, and gums), throat or neck, trouble breathing, rash with peeling skin, blisters in your mouth

- The most common side effects of CHAMPIX include:
 - nausea
 - sleep problems (trouble sleeping or vivid, unusual, or strange dreams)
 - constipation
 - gas
 - vomiting

Tell your doctor about side effects that bother you or that do not go away.

These are not all the side effects of CHAMPIX. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects.

How should I store CHAMPIX?

- Do not store CHAMPIX above 30°C.
- **Keep CHAMPIX and all medicines out of the reach of children.**

General information about the safe and effective use of CHAMPIX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use **CHAMPIX** for a condition for which it was not prescribed. Do not give your **CHAMPIX** to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about CHAMPIX that is written for healthcare professionals. If you are motivated to quit smoking and did not succeed during prior CHAMPIX treatment for reasons other than side effects, or if you returned to smoking after treatment, speak with your doctor about whether another course of CHAMPIX therapy may be right for you.

What are the ingredients in CHAMPIX?

Active ingredient: varenicline tartrate

Inactive ingredients: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, Opadry® White (for 0.5 mg), Opadry® Blue (for 1 mg), and Opadry® Clear (for both 0.5 mg and 1 mg)

Rx only

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