

MEDICATION GUIDE

CHANTIX®

(varenicline) Tablets

Read the Medication Guide that comes with CHANTIX 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 CHANTIX?

Some patients have had changes in behavior, agitation, depressed mood, and suicidal thoughts or actions while using CHANTIX to help them quit smoking. Some people had these symptoms when they began taking CHANTIX, and others developed them after several weeks of treatment or after stopping CHANTIX. If either you, your family or caregiver notice agitation, depressed mood, or changes in behavior that are not typical for you, or if you develop suicidal thoughts or actions, stop taking CHANTIX and call your doctor right away.

When you try to quit smoking, with or without CHANTIX, 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. Sometimes quitting smoking can lead to worsening of mental health problems that you already have, such as depression.

Before taking CHANTIX, 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 CHANTIX.

See **“What are the possible side effects of CHANTIX?”**

What is CHANTIX?

CHANTIX is a prescription medicine to help adults 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.

CHANTIX is not recommended for children under 18 years of age.

CHANTIX has not been studied along with other treatments for stopping smoking.

What should I tell my doctor before taking CHANTIX?

Tell your doctor about all of your medical conditions including if you:

- have ever had depression or other mental health problems. See “What is the most important information I should know about CHANTIX?”
- have kidney problems or get kidney dialysis. Your doctor may prescribe a lower dose of CHANTIX for you.
- have any allergies. See the end of this Medication Guide for a complete list of ingredients in CHANTIX.
- are pregnant or plan to become pregnant. CHANTIX has not been studied in pregnant women. It is not known if CHANTIX will harm your unborn baby. It is best to stop smoking before you get pregnant.
- are breastfeeding. Although it was not studied in humans, CHANTIX may pass into breast milk. You and your doctor should talk about the best way to feed your baby if you take CHANTIX.

Tell your doctor about all your other medicines including prescription and nonprescription medicines, vitamins and herbal supplements. Especially, tell your doctor if you take:

- insulin
- asthma medicines
- blood thinners.

When you stop smoking, there may be a change in how these and other medicines work for you.

You should not use CHANTIX while using other treatments 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 CHANTIX?

- Take CHANTIX exactly as prescribed by your doctor.
 1. Choose a **quit date** when you will stop smoking.
 2. Start taking CHANTIX 1 week (7 days) before your **quit date**. This lets CHANTIX build up in your body. You can keep smoking during this time. Make sure that you try and stop smoking on your **quit date**. If you slip-up and smoke, try again. Some people need to take CHANTIX for a few weeks for CHANTIX to work best.
 3. Take CHANTIX after eating and with a full glass (8 ounces) of water.
 4. Most people will take CHANTIX for up to 12 weeks. If you have completely quit smoking by 12 weeks, your doctor may prescribe CHANTIX for another 12 weeks to help you stay cigarette-free.
- CHANTIX 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

- This dosing schedule may not be right for everyone. Talk to your doctor if you are having side effects such as nausea, strange dreams, or sleep problems. Your doctor may want to reduce your dose.

- If you miss a dose of CHANTIX, take it as soon as you remember. If it is close to the time for your next dose, wait. Just take your next dose at your regular dose.

What should I avoid while taking CHANTIX?

Use caution driving or operating machinery until you know how quitting smoking with CHANTIX may affect you.

What are the possible side effects of CHANTIX?

- **Some patients have had new or worse mental health problems.** See “What is the most important information I should know about CHANTIX?”
- The most common side effects of CHANTIX 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 CHANTIX. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store CHANTIX?

- Store CHANTIX at room temperature, 59 to 86°F (15 to 30°C).
- Safely dispose of CHANTIX that is out of date or no longer needed.
- **Keep CHANTIX and all medicines out of the reach of children.**

General information about CHANTIX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use **CHANTIX** for a condition for which it was not prescribed.

Do not give your **CHANTIX** to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about CHANTIX. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about CHANTIX that is written for healthcare professionals.

For more about CHANTIX and tips on how to quit smoking, go to www.CHANTIX.com
Or call 1-877-CHANTIX (877-242-6849).

What are the ingredients in CHANTIX?

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



LAB-0328-6.0

Revised May 2008

This Medication Guide has been approved by the U.S. Food and Drug Administration.