

NDA 021928 CHANTIX (varenicline) Tablets

Smoking Cessation

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I. GOAL

To mitigate the potential risk of serious neuropsychiatric symptoms in patients taking Chantix by training patients about appropriate monitoring for psychiatric symptoms unusual to the individual, such as agitation, depressed mood and changes in behavior or if the patient develops suicidal ideation and suicidal behavior.

II. REMS ELEMENTS

A. Medication Guide

Pfizer will provide Medication Guides to pharmacists to be given to patients each time Chantix is dispensed to increase patient knowledge of how to safely and effectively use Chantix. Pfizer must provide copies of the Medication Guide for each unit of use bottle. Pfizer will make tear pads containing the Medication Guide available in pharmacies for direct distribution to patients.

B. Timetable for Assessments

REMS Assessments will be submitted to FDA 18 months, 3 years, and 7 years following REMS approval. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Pfizer will submit each assessment so that it will be received by the FDA on or before the due date.

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 people have had changes in behavior, hostility, 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 you, your family, or caregiver notice agitation, hostility, depression or changes in behavior or thinking that are not typical for you, or you develop any of the following symptoms, stop taking CHANTIX and call your healthcare provider right away:

- 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 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. 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.

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?”**

Some people can have allergic reactions to CHANTIX. 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 CHANTIX and get medical attention right away.

Some people can have serious skin reactions while taking CHANTIX. 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, stop taking CHANTIX and see your doctor right away.

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 people under 18 years of age.

CHANTIX has not been studied 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 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 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 CHANTIX may affect you. Some people who use CHANTIX may feel sleepy, dizzy, or have trouble concentrating, that can make it hard to drive or perform other activities safely.

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



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Revised July 2009

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