

PATIENT INFORMATION

CHANTIX™

(varenicline) Tablets

Read the patient information 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 CHANTIX?

CHANTIX is a prescription medicine to help adults stop smoking.

WHO SHOULD NOT TAKE CHANTIX?

CHANTIX has not been studied in children under 18 years of age. CHANTIX is not recommended for children under 18 years of age.

Do not take CHANTIX if you are allergic to anything in it. See a complete list of ingredients at the end of this leaflet.

WHAT SHOULD I TELL MY DOCTOR BEFORE STARTING CHANTIX?

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

- have kidney problems or get kidney dialysis. Your doctor may prescribe a lower dose of CHANTIX for you.
- have experienced depression or other mental health problems.
- 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, CHANTIX may pass into breast milk. You and your doctor should discuss alternative ways 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.

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

HOW DO I TAKE CHANTIX?

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, try again. Some people need 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 keep taking CHANTIX for up to 12 weeks. If you have completely quit smoking by 12 weeks, ask your doctor if another 12 weeks of CHANTIX may 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), 1 tablet each day
<u>Day 4 to Day 7</u>	<ul style="list-style-type: none">• <u>White</u> tablet (0.5 mg), twice a day• 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) twice a day• 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 or sleep problems. Your doctor may want to reduce your dose.
- If you miss a dose, take it as soon as you remember. If it is close to the time for your next dose, wait. Just take your next regular dose.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF CHANTIX?

The most common side effects of CHANTIX include:

- nausea
- sleep disturbance (trouble sleeping or vivid, unusual, or increased dreaming)
- 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.

Tell your doctor if you experience agitation, depressed mood or suicidal thoughts. These symptoms have been reported in patients trying to stop smoking with or without Chantix. It is not known if these symptoms are related to Chantix.

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

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 conditions other than those described in patient information leaflets. 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 leaflet 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.

To find out more about CHANTIX and tips on how to quit smoking:

- Go to the CHANTIX website at www.CHANTIX.com.
- Call 1-877-CHANTIX (877-242-6849).

WHAT IS IN CHANTIX?

Active ingredient: varenicline tartrate

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

Rx only



Distributed by

Pfizer Labs

Division of Pfizer Inc, NY, NY 10017

LAB-0328-5.0

November 2007