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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.

Day 1 to Day 3	• White tablet (0.5 mg) • Take 1 tablet each day
Day 4 to Day 7	• White tablet (0.5 mg) • Take 1 in the morning and 1 in the evening
Day 8 to end of treatment	• Blue 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

Distributed by

Pfizer Labs

Division of Pfizer Inc, NY, NY 10017

LAB-0328-8.0

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

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Drugs

Important Information on Chantix (varenicline)

[5/16/2008]: The issues described in this communication have been addressed in the product labeling and FDA has approved the Medication Guide. If either you, your family or caregiver notice agitation, depressed mood, or changes in behavior that are not typical for you, or if you have suicidal thoughts or actions, stop taking Chantix and call your doctor right away.

FDA is issuing this public health advisory to alert patients, caregivers, and healthcare professionals to important changes to Chantix prescribing information. Chantix is a medicine used to help patients stop smoking.

At the request of FDA, Pfizer, the manufacturer of Chantix, has updated the Chantix prescribing information to include warnings about the possibility of severe changes in mood and behavior in patients taking Chantix. FDA is highlighting the following related important safety information on Chantix:

- **Patients should tell their doctor about any history of psychiatric illness prior to starting Chantix.** Chantix may cause worsening of a current psychiatric illness even if it is currently under control and may cause an old psychiatric illness to reoccur.
- **Healthcare professionals, patients, patients' families, and caregivers should be alert to and monitor for changes in mood and behavior in patients treated with Chantix.**
  Symptoms may include anxiety, nervousness, tension, depressed mood, unusual behaviors and thinking about or attempting suicide. **In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of varenicline therapy.**
- **Patients taking Chantix should immediately report changes in mood and behavior to their doctor.**
- **Patients taking Chantix may experience vivid, unusual, or strange dreams.**
- **Patients taking Chantix may experience impairment of the ability to drive or operate heavy machinery.**

While Chantix has demonstrated clear evidence of efficacy, it is important to consider these safety concerns and alert patients that they are possible.

FDA first informed the public about the possibility of severe changes in mood and behavior in the November 20, 2007 *FDA Early Communication About an Ongoing Safety*

Review. At that time, information about severe changes in mood and behavior in patients taking Chantix was added to the Chantix label with an explanation that the link between Chantix and these symptoms was unclear. As FDA's review of the data has progressed it has become increasingly likely that the severe changes in mood and behavior may be related to Chantix. As a result, FDA worked with Pfizer, the manufacturer of Chantix, to add warnings to the Chantix label about the possibility of severe changes in mood and behavior so healthcare professionals and patients can be more alert to this information. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients.

FDA will update the public about any new information from FDA's continuing review of the data or new information that it receives on Chantix and severe changes in mood and behavior. FDA may consider additional changes to the Chantix prescribing information as the data review and conclusions warrant.

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Safety

Chantix (varenicline)

Audience: Healthcare professionals, consumers

[UPDATE 05/16/2008] FDA informed healthcare professionals and patients that as the Agency's review of Chantix safety data has progressed, it appears increasingly likely that there is an association between Chantix and serious neuropsychiatric symptoms. Prescribing information for Chantix was revised to include this safety information in the WARNINGS and PRECAUTIONS sections of the label, and a Medication Guide for patients is also available. If patients, their families, or caregivers notice agitation, depressed mood, or changes in behavior that are not typical for the patient or if the patient has suicidal thoughts or actions, the patient should stop taking Chantix and contact their healthcare professional.

[Posted 11/20/2007] FDA informed healthcare professionals of reports of suicidal thoughts and aggressive and erratic behavior in patient who have taken Chantix, a smoking cessation product. There are also reports of patients experiencing drowsiness that affected their ability to drive or operate machinery. FDA is currently reviewing these cases, along with other recent reports. A preliminary assessment reveals that many of the cases reflect new-onset of depressed mood, suicidal ideation, and changes in emotion and behavior within days to weeks of initiating Chantix treatment. The role of Chantix in these cases is not clear because smoking cessation, with or without treatment, is associated with nicotine withdrawal symptoms and has also been associated with the exacerbation of underlying psychiatric illness. However, not all patients described in the cases had preexisting psychiatric illness and not all had discontinued smoking.

Healthcare professionals should monitor patients taking Chantix for behavior and mood changes. Patients taking this product should report behavior or mood changes to their doctor and use caution when driving or operating machinery until they know how quitting smoking with Chantix may affect them.

[May 2008 - Label - Pfizer]
[May 16, 2008 - Drug Information Page - FDA]
[May 16, 2008 - Medication Guide - Pfizer]
[May 16, 2008 - Information for Healthcare Professionals sheet - FDA]
[November 20, 2007 - Ongoing Safety Review: Varenicline (marketed as Chantix) - FDA]

This article appears on FDA's Consumer Updates page, which features the latest on all FDA-regulated products.

Date Posted: February 5, 2008

For More Information

- FDA Issues Public Health Advisory on Chantix

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For Consumers

New Safety Warnings for Chantix

Search Consumer Updates

FDA issued a Public Health Advisory on Feb. 1, 2008, to alert health care providers, patients, and caregivers to new safety warnings concerning Chantix (varenicline). Chantix is a prescription medication used to help people stop smoking.

Chantix was approved by FDA in May 2006. In November 2007, FDA issued an Early Communication to tell the public and health care providers that the agency was evaluating adverse event reports on Chantix related to changes in behavior, agitation, depressed mood, suicidal thoughts, and attempted and completed suicide.

As FDA continues its review of the adverse event reports, it appears increasingly likely that there may be an association between Chantix and serious mood and behavior symptoms.

FDA has requested that Pfizer, the manufacturer of Chantix, give the safety information a more prominent position on the drug's prescribing information, or labeling. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients.

"Chantix has proven to be effective in smokers motivated to quit, but patients and health care professionals need the latest safety information to make an informed decision regarding whether or not to use this product," says Bob Rappaport, M.D., Director of FDA's Division of Anesthesia, Analgesia and Rheumatology Products. "Patients should talk with their doctors about this new information and whether Chantix is the right drug for them."

Tips for Consumers

- Tell your health care provider about any history of psychiatric illness before you start taking Chantix.
- Immediately tell a doctor if you or someone you care for has any changes in mood and behavior while being treated with Chantix. In most cases, mood and behavior changes developed during treatment, but some people developed symptoms after they stopped taking Chantix.
- Be aware that vivid, unusual, or strange dreams may occur while taking Chantix.
- Chantix may affect your ability to drive or operate machinery.

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Drugs

Information for Healthcare Professionals: Varenicline (marketed as Chantix)

FDA ALERT [2/1/2008]: FDA is issuing this Alert to highlight important revisions to the WARNINGS and PRECAUTIONS sections of the full prescribing information for Chantix regarding serious neuropsychiatric symptoms.

Serious neuropsychiatric symptoms have occurred in patients taking Chantix. These symptoms include changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide. While some patients may have experienced these types of symptoms and events as a result of nicotine withdrawal, some patients taking Chantix who experienced serious neuropsychiatric symptoms and events had not yet discontinued smoking. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of Chantix therapy.

FDA first informed the public about the possibility of serious neuropsychiatric symptoms in the November 20, 2007 *FDA Early Communication About an Ongoing Safety Review*. At that time, information about serious neuropsychiatric symptoms in patients taking Chantix was added to the POST-MARKETING EXPERIENCE section of the prescribing information. As FDA's review of the issue has progressed, it appears increasingly likely that there is an association between Chantix and serious neuropsychiatric symptoms. As a result, FDA requested that Pfizer, the manufacturer of Chantix, elevate the prominence of this safety information to the WARNINGS and PRECAUTIONS sections of the Chantix prescribing information. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients.

[5/16/2008]: The issues described in this communication have been addressed in the product labeling and FDA has approved the Medication Guide. If either you, your family or caregiver notice agitation, depressed mood, or changes in behavior that are not typical for you, or if you have suicidal thoughts or actions, stop taking Chantix and call your doctor right away.

This information reflects FDA's current analysis of data available concerning this drug. FDA is not advising practitiones to discontinue prescribing the product and intends to provide updated information when it becomes available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program using the contact information at the bottom of this sheet.

At the request of FDA, the Chantix full prescribing information includes new information in the WARNINGS and PRECAUTIONS sections about the possibility of serious neuropsychiatric symptoms (changes in behavior, agitation, depressed mood, and

suicidal ideation and behavior) in patients taking Chantix. FDA is working with Pfizer, the manufacturer of Chantix, to finalize a Medication Guide for patients.

Recommendations and Considerations for Healthcare Professionals

- **Healthcare providers should monitor all patients taking Chantix for symptoms of serious neuropsychiatric symptoms.** Symptoms include changes in behavior, agitation, depressed mood, suicidal ideation, and suicidal behavior. These symptoms have sometimes occurred in patients without pre-existing psychiatric illness and have worsened in some patients with pre-existing psychiatric illness treated with Chantix. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of Chantix therapy.
- **Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder, may experience worsening of their pre-existing psychiatric illness while taking Chantix.** Patients with serious psychiatric illness did not participate in the pre-marketing studies of Chantix. The safety and efficacy of Chantix in these patients has not been established.
- **While Chantix has demonstrated clear evidence of efficacy, it is important to consider these safety concerns and alert patients about these risks.**

Information for the patient: *Physicians who prescribe Chantix should discuss with their patients, patients' families, and caregiver the following:*

- **Tell the doctor about any history of psychiatric illness prior to starting Chantix.** Patients taking Chantix have experienced worsening of current psychiatric illness, even if it is currently under control, and the reoccurrence of previous psychiatric illness.
- **Be alert to changes in mood and behavior.** Symptoms include strange thoughts or behaviors, depressed mood, and thinking about or attempting suicide.
- **Immediately report changes in mood and behavior to the doctor.**
- **Vivid, unusual, or strange dreams may occur while taking Chantix.**

Background Information and Data

FDA first informed the public about the possibility of serious neuropsychiatric symptoms in the November 20, 2007 *FDA Early Communication About an Ongoing Safety Review*. At that time, information about serious neuropsychiatric symptoms in patients taking Chantix was added to the POST-MARKETING EXPERIENCE section of the prescribing information. As FDA's review of the data has progressed and FDA has received additional information, it has become increasingly likely that there is an association between Chantix and serious neuropsychiatric symptoms. As a result, FDA requested that Pfizer, the manufacturer of Chantix, add the information to the WARNINGS and PRECAUTIONS sections of the Chantix prescribing information so that healthcare professionals and patients can be more alert to these issues. In addition, FDA is

working with Pfizer to finalize a Medication Guide for patients.

- FDA will update healthcare professionals about new information from FDA's continuing review of the data or new information that it receives on Chantix and serious neuropsychiatric symptoms. FDA may consider additional regulatory action as the data review and conclusions warrant.

Contact Us

- 1-800-332-1088
- 1-800-FDA-0178 Fax
- **Report a Serious Problem**

MedWatch Online

Regular Mail: Use postage-paid FDA Form 3500

Mail to: MedWatch 5600 Fishers Lane

Rockville, MD 20852-9787

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News & Events

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE
February 1, 2008

Media Inquiries:
Susan Cruzan, 301-827-6242
Rita Chappelle, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Issues Public Health Advisory on Chantix

Agency requests that manufacturer add new safety warnings for smoking cessation drug

The U.S. Food and Drug Administration (FDA) today issued a Public Health Advisory to alert health care providers, patients, and caregivers to new safety warnings concerning Chantix (varenicline), a prescription medication used to help patients stop smoking.

On Nov. 20, 2007, FDA issued an Early Communication to the public and health care providers that the agency was evaluating postmarketing adverse event reports on Chantix related to changes in behavior, agitation, depressed mood, suicidal ideation, and actual suicidal behavior.

As the agency's review of the adverse event reports proceeds, it appears increasingly likely that there may be an association between Chantix and serious neuropsychiatric symptoms. As a result, FDA has requested that Pfizer, the manufacturer of Chantix, elevate the prominence of this safety information to the warnings and precautions section of the Chantix prescribing information, or labeling. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients. This is an example of FDA working with drug manufacturers throughout products' lifecycles to keep health care professionals and patients informed of new and emerging safety data.

"Chantix has proven to be effective in smokers motivated to quit, but patients and health care professionals need the latest safety information to make an informed decision regarding whether or not to use this product," said Bob Rappaport, M.D., director of the FDA's Division of Anesthesia, Analgesia and Rheumatology Products. "While Chantix has demonstrated clear evidence of efficacy, it is important to consider these safety concerns and alert the public about these risks. Patients should talk with their doctors about this new information and whether Chantix is the right drug for them, and health care professionals should closely monitor patients for behavior and mood changes if they are taking this drug."

Chantix was approved by FDA in May 2006 as a smoking cessation drug. Chantix acts at sites in the brain affected by nicotine and may help those who wish to stop smoking by providing some nicotine effects to ease the withdrawal symptoms and by blocking the

effects of nicotine from cigarettes if users resume smoking.

In the Public Health Advisory and a Health Care Professional Sheet that was also issued today, FDA emphasized the following safety information for patients, caregivers, and health care professionals:

- **Patients should tell their health care provider about any history of psychiatric illness prior to starting Chantix.** Chantix may cause worsening of current psychiatric illness even if it is currently under control. It may also cause an old psychiatric illness to reoccur. FDA notes that patients with these illnesses were not included in the studies conducted for the drug's approval.
- **Health care professionals, patients, patients' families, and caregivers should be alert to and monitor for changes in mood and behavior in patients treated with Chantix.** Symptoms may include anxiety, nervousness, tension, depressed mood, unusual behaviors and thinking about or attempting suicide. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of varenicline therapy.
- **Patients should immediately report changes in mood and behavior to their doctor.**
- **Vivid, unusual, or strange dreams may occur while taking Chantix.**
- **Patients taking Chantix may experience impairment of the ability to drive or operate heavy machinery.**

FDA will continue to update health care professionals with new information from FDA's continuing review or if new information is received on Chantix and serious neuropsychiatric symptoms. FDA may consider requesting further revisions to the labeling or taking other regulatory action as the agency's continuing reviews and conclusions warrant.

For more information:
http://www.fda.gov/cder/drug/infopage/varenicline/default.htm

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RSS Feed for FDA News Releases [what is RSS?]

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Drugs

Early Communication About an Ongoing Safety Review of Varenicline (marketed as Chantix)

This information is not current. The FDA has issued new information about this safety issue, please see Varenicline (marketed as Chantix) Information

This information reflects FDA's current analysis of available data concerning these drugs. Posting this information does not mean that FDA has concluded there is a causal relationship between the drug products and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing these products. FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action. FDA intends to update this document when additional information or analyses become available.

FDA has received reports of suicidal thoughts and aggressive and erratic behavior in patients who have taken Chantix, a smoking cessation product.

Suicidal Thoughts

The manufacturer of Chantix, Pfizer, Inc., recently submitted to FDA postmarketing cases describing suicidal ideation and occasional suicidal behavior. FDA currently is reviewing these cases, along with a number of recent reports in the popular press and internet sites. A preliminary assessment reveals that many of the cases reflect new-onset of depressed mood, suicidal ideation, and changes in emotion and behavior within days to weeks of initiating Chantix treatment. The role of Chantix in these cases is not clear because smoking cessation, with or without treatment, is associated with nicotine withdrawal symptoms and has also been associated with the exacerbation of underlying psychiatric illness. However, not all patients described in these cases had pre-existing psychiatric illness and not all had discontinued smoking.

Aggressive and Erratic Behavior

FDA is aware of a highly-publicized case of erratic behavior leading to the death of a patient using Chantix to attempt to quit smoking. Although other factors, including alcohol consumption, appear to have played a part in this specific case, FDA asked Pfizer for additional cases that might be similar. We are currently evaluating the material Pfizer submitted in response to our request.

Drowsiness

FDA is evaluating reports from Pfizer of drowsiness in patients taking Chantix. Reports described patients who experienced drowsiness that affected their ability to drive or operate machinery.

FDA recommends the following:

- Healthcare professionals should monitor patients taking Chantix for behavior and mood changes.
- Patients taking Chantix should contact their doctors if they experience behavior or mood changes.
- Patients should use caution when driving or operating machinery until they know how quitting smoking with Chantix may affect them.

This early communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews of drugs. FDA is working with Pfizer, Inc., to further evaluate the potential association between Chantix and suicidal thoughts, aggressive and erratic behavior, and impairment that affects one's ability to drive or operate machinery. FDA is working to complete the analysis of the materials submitted by Pfizer. As soon as this analysis is completed, FDA will communicate its conclusions and recommendations to the public.

The FDA urges both healthcare professionals and patients to report side effects from the use of Chantix to the FDA's MedWatch Adverse Event Reporting program, using the contact information at the bottom of this page.

Contact Us

- 1-800-332-1088
- 1-800-FDA-0178 Fax
- **Report a Serious Problem**

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