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## Varenicline

pronounced as (var en' I kleen)

### Why is this medication prescribed?

Varenicline is used along with education and counseling to help people stop smoking. Varenicline is in a class of medications called smoking cessation aids. It works by blocking the pleasant effects of nicotine (from smoking) on the brain.

### How should this medicine be used?

Varenicline comes as a tablet to take by mouth. It is usually taken once a day at first and then twice a day in the morning and evening. Take varenicline with a full glass of water (8 ounces [240 mL]) after eating. Take varenicline at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take varenicline exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor will probably start you on a low dose of varenicline and gradually increase your dose over the first week of treatment.

### There are 3 ways that you can take varenicline to help you quit smoking.

- You can set a quit date to stop smoking and start taking varenicline 1 week before that date. You may continue to smoke during this first week of varenicline treatment, but make sure to try to stop smoking on the quit date you have chosen.
- You may start taking varenicline and then quit smoking between 8 and 35 days after starting treatment with varenicline.
- If you are not sure you are able or if you do not want to quit smoking suddenly, you can start taking varenicline and stop smoking slowly over 12 weeks of treatment. For weeks 1–4, you should try to smoke only half as many of your normal number of cigarettes each day. For weeks 5–8, you should try to smoke only one quarter of your starting daily number of cigarettes. For weeks 9–12, you should continue to try to smoke fewer cigarettes each day until you are no longer smoking at all. Aim to quit completely by the end of 12 weeks or sooner if you feel ready.

It may take several weeks for you to feel the full benefit of varenicline. You may slip and smoke during your treatment. If this happens, you may still be able to stop smoking. Continue to take varenicline and to try not to smoke.

You will probably take varenicline for 12 weeks. If you have completely stopped smoking at the end of 12 weeks, your doctor may tell you to take varenicline for another 12 weeks. This may help keep you from starting to smoke again.

If you have not stopped smoking at the end of 12 weeks, talk to your doctor. Your doctor can try to help you understand why you were not able to stop smoking and make plans to try to quit again.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with varenicline and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website

(<http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088569.pdf>

[<http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088569.pdf>] ) or the manufacturer's website to obtain the Medication Guide.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking varenicline,

- tell your doctor and pharmacist if you are allergic to varenicline or any other medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants ("blood thinners") such as warfarin (Coumadin, Jantoven); insulin; other medications to help you stop smoking such as bupropion (Aplenzin, Forfivo, Wellbutrin, Zyban, in Contrave) and nicotine gum, inhaler, lozenges, nasal spray, or skin patches; and theophylline (Elixophyllin, Theo-24, Theocron). Your doctor may need to change the doses of some of your medications once you stop smoking.
- tell your doctor if you have ever had withdrawal symptoms when you tried to quit smoking in the past and if you have or have ever had epilepsy (seizures); or heart, blood vessel, or kidney disease
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking varenicline, call your doctor. If you are breastfeeding while taking varenicline, watch your baby carefully for seizures, and vomiting or spitting up more often than usual. Call your doctor immediately if your baby experiences any of these symptoms.
- you should know that varenicline may make you drowsy, dizzy, lose consciousness, or have difficulty concentrating. There have been reports of traffic accidents, near-miss accidents, and other types of injuries in people who were taking varenicline. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that some people have had changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts (thinking about harming or killing oneself or planning or trying to do so) while taking varenicline. The role of varenicline in causing these mood changes is unclear since people who quit smoking with or without medication may experience changes in their mental health due to nicotine withdrawal. However, some of these symptoms occurred in people who were taking varenicline and continued to smoke. Some people had these symptoms when they began taking varenicline, and others developed them after several weeks of treatment or after stopping varenicline.

These symptoms have occurred in people without a history of mental illness and have worsened in people who already had a mental illness. Tell your doctor if you have or have ever had depression, bipolar disorder (mood that changes from depressed to abnormally excited), schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions), or other mental illnesses. If you experience any of the following symptoms, stop taking varenicline and call your doctor immediately: suicidal thoughts or actions; new or worsening depression, anxiety, or panic attacks; agitation; restlessness; angry or violent behavior; acting dangerously; mania (frenzied, abnormally excited mood or talking); abnormal thoughts or sensations; hallucinations (seeing things or hearing voices that do not exist); feeling that people are against you; feeling confused; or any other sudden or unusual changes in behavior, thinking, or mood. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own. Your doctor will monitor you closely until your symptoms get better.

- ask your doctor about the safe use of alcoholic beverages while you are taking varenicline. Varenicline can increase the effects of alcohol,
- ask your doctor for advice and for written information to help you stop smoking. You are more likely to stop smoking during your treatment with varenicline if you get information and support from your doctor.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Varenicline may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- nausea
- constipation
- diarrhea
- gas
- abdominal pain
- vomiting
- heartburn
- bad taste in the mouth
- dry mouth
- increased or decreased appetite
- toothache

- trouble falling asleep or staying asleep
- unusual dreams or nightmares
- headache
- lack of energy
- back, joint, or muscle pain
- abnormal menstrual cycles

**Some side effects can be serious. If you experience any of these symptoms or those listed in the SPECIAL PRECAUTIONS sections, stop taking varenicline and call your doctor or get medical help immediately:**

- swelling of the face, throat, tongue, lips, gums, eyes, neck, hands, arms, feet, ankles, or lower legs
- hoarseness
- difficulty swallowing or breathing
- rash
- swollen, red, peeling, or blistering skin
- blisters in the mouth
- pain, squeezing, or pressure in the chest
- pain or discomfort in one or both arms, back, neck, jaw, or stomach
- shortness of breath
- sweating
- nausea, vomiting, or lightheadedness with chest pain
- slow or difficult speech
- sudden weakness or numbness of an arm or leg, especially on one side of the body
- calf pain while walking
- seizures
- sleepwalking

In clinical studies, people who took varenicline were more likely to have a heart attack, a stroke, or other serious problems with their heart or blood vessels than people who did not receive this medication. However, people who smoke also have a higher risk of developing these problems. Talk to your doctor about the risks and benefits of taking varenicline, especially if you have or ever had heart or blood vessel disease.

Varenicline may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online

(<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Chantix<sup>®</sup>

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

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