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2. Varenicline

Varenicline

Pronunciation: *var-ren-i-cline*

Generic name: varenicline

Brand name: Chantix (discontinued)

Dosage form: oral tablet

Drug classes: [Cholinergic agonists](#), [Smoking cessation agents](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Aug 4, 2024.

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What is varenicline?

Varenicline is a smoking cessation aid that is used alongside education and counseling to help people stop smoking. Varenicline works by binding to nicotinic receptors, stimulating these receptors at a much lower level than nicotine, while at the same time preventing nicotine from binding to these same receptors. This decreases nicotine cravings and withdrawal symptoms that happen when people stop smoking. It belongs to the class of medicines called smoking cessation aids.

Varenicline was FDA-approved on May 10, 2006, under the brand Chantix. The Chantix brand has been discontinued, but varenicline generics are available.

Varenicline side effects

Nausea is the most common side effect reported with varenicline, experienced by up to 30% of people taking it. Reducing the dose may help with this side effect.

Other **common side effects of varenicline** affecting 5% or more people who take it include:

- sleep problems (trouble sleeping or vivid, unusual, or strange dreams)
- constipation
- gas
- vomiting.

When you try to quit smoking, with or without varenicline, you may have symptoms that may be due to nicotine withdrawal, such as:

- an urge to smoke
- a depressed mood

- trouble sleeping
- irritability
- frustration
- anger
- feeling anxious
- difficulty concentrating
- restlessness
- a decreased heart rate
- increased appetite
- weight gain.

Serious side effects and warnings

Some people have experienced the following serious side effects while taking varenicline to help them quit smoking.

New or worse mental health problems, such as changes in behavior or thinking, aggression, hostility, agitation, depressed mood, or suicidal thoughts or actions. Some people had these symptoms when they began taking varenicline, and others developed them after several weeks of treatment, or after stopping treatment. These symptoms happened more often in people who had a history of mental health problems before taking varenicline than in people without a history of mental health problems.

- Stop taking varenicline and call your healthcare provider right away if you, your family, or your caregiver notice any of these symptoms. Work with your healthcare provider to decide whether you should continue to take varenicline. In many people, these symptoms went away after stopping varenicline, but in some people, symptoms continued despite stopping it. You need to follow up with your healthcare provider until your symptoms go away.

Some people have even experienced **suicidal thoughts** when trying to quit smoking with or without medication such as varenicline. Sometimes quitting smoking can lead to worsening mental health problems that you already have, such as depression.

Seizures. Some people have had seizures during treatment with varenicline. In most cases, the seizures have happened during the first month of treatment. If you have a seizure during treatment with varenicline, stop taking it and contact your healthcare provider right away.

New or worse heart or blood vessel (cardiovascular) problems, mostly in people, who already have cardiovascular problems. Tell your healthcare provider if you have any changes in symptoms during treatment with varenicline. Get emergency medical help right away if you have any of the following symptoms of a heart attack, including:

- chest discomfort (uncomfortable pressure, squeezing, fullness, or pain) that lasts more than a few minutes, or that goes away and comes back
- pain or discomfort in one or both arms, back, neck, jaw, or stomach
- shortness of breath, sweating, nausea, vomiting, or a lightheaded feeling associated with chest discomfort.

Sleepwalking can happen with varenicline, and can sometimes lead to behavior that is harmful to you or other people, or to property. Stop taking varenicline and tell your healthcare provider if you start sleepwalking.

Allergic reactions can happen with varenicline. Some of these allergic reactions can be life-threatening.

Serious skin reactions, including rash, swelling, redness, and peeling of the skin. Some of these skin reactions can become life-threatening. Stop taking varenicline and get medical help right away if you have any of the following symptoms:

- swelling of the face, mouth (tongue, lips, and gums), throat or neck
- trouble breathing
- rash with peeling skin
- blisters in your mouth.

Tell your healthcare provider about side effects that bother you or do not go away.

Varenicline is not effective in children 16 years of age and under and should not be used in children.

It is not known if varenicline is safe and effective when used with other stop-smoking medicines.

These are not all the side effects of varenicline. Ask your healthcare provider or pharmacist for more information. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

 [Varenicline side effects](#) (more detail)

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Before taking

Do not take varenicline if you have had a serious allergic or skin reaction to varenicline, Chantix, or any inactive ingredients in the tablets. Symptoms may include:

- swelling of the face, mouth (tongue, lips, gums), throat or neck
- trouble breathing
- rash, with peeling skin
- blisters in your mouth.

Before taking varenicline, tell your healthcare provider if you have ever had depression or other mental health problems. Also tell your healthcare provider about any symptoms you had during other times you tried to quit smoking, with or without varenicline.

Tell your healthcare provider if you:

- use other treatments to quit smoking. Using varenicline with a nicotine patch may cause nausea, vomiting, headache, dizziness, upset stomach, and tiredness to happen more often than if you just use a nicotine patch alone.
- have kidney problems or get kidney dialysis. Your healthcare provider may prescribe a lower dose of varenicline for you.
- have a history of seizures
- drink alcohol
- have heart or blood vessel problems
- have any other medical conditions
- are pregnant or planning to become pregnant
- are breastfeeding.

Pregnancy

It is not known if varenicline will harm an unborn baby.

Breastfeeding

It is not known if varenicline passes into breast milk. If you breastfeed and take varenicline, monitor your baby for seizures as well as spitting up or vomiting more than normal.

 [Varenicline pregnancy and breastfeeding warnings](#) (more detail)

How should I take varenicline?

Varenicline is an oral tablet that is taken twice a day. The most common way to start taking varenicline is at least one week before you quit, at a low dose (varenicline 0.5 mg), which is gradually increased over 8 days to varenicline 1 mg twice a day.

- Take varenicline with food or soon after eating and with a full glass of water to minimize potential nausea from the medications.
- Varenicline does not contain nicotine, so it works differently than nicotine replacement medicines.

3 ways to take varenicline

Choose a quit date when you will stop smoking. Start taking varenicline 1 week (7 days) before your quit date. Take varenicline for 12 weeks. Start with a low dose and gradually increase the dose as per the varenicline dosage information below. Your doctor may suggest you continue varenicline for another 12 weeks if you have stopped smoking in this time.

OR

Start taking varenicline before you choose a quit date. Decide on a date to quit smoking after taking varenicline for at least 8 days but before you have taken it for 35 days. Take varenicline for 12 weeks in total. Your doctor may suggest you continue varenicline for another 12 weeks if you have stopped smoking in this time.

OR

If you are sure that you are not able or willing to quit smoking right away, start taking varenicline and cut down on how much you smoke during the first 12 weeks of treatment. Specifically:

- Weeks 1 through 4: Reduce your smoking to reach one-half of your starting daily number of cigarettes. Example: If you usually smoke 20 cigarettes each day, reduce your smoking to 10 cigarettes each day during weeks 1 through 4.
- Weeks 5 through 8: Reduce your smoking to reach one-quarter of your starting daily number of cigarettes. Example: If you usually smoked 20 cigarettes each day, reduce your smoking to 5 cigarettes each day during weeks 5 through 8.
- Weeks 9 through 12: Keep reducing your smoking until you are no longer smoking (you reach zero cigarettes each day).
- Aim to quit by the end of the 12th week of treatment, or sooner if you feel ready. Continue to take varenicline for another 12 weeks, for a total of 24 weeks of treatment.
- Starting varenicline before your quit date gives it time to build up in your body. You can keep smoking during this time.

These dosing schedules may not be right for everyone. Talk to your healthcare provider if you are having side effects such as nausea, strange dreams, or sleep problems. Your healthcare provider may want to reduce your dose.

Varenicline dosage

Take varenicline exactly as prescribed by your healthcare provider.

The usual starting dose of varenicline is 0.5mg. This dose is slowly increased as follows:

- **Day 1 to 3:** 0.5 mg once a day
- **Day 4 to 7:** 0.5 mg twice a day
- **Day 8 to end of treatment:** 1 mg twice a day

Make sure that you try to stop smoking on the quit date you have decided. If you slip up and smoke, try again. Some people need to take varenicline for several weeks before it works.

- Most people take varenicline for 12 weeks initially. If you have completely quit smoking by 12 weeks, your healthcare provider may prescribe varenicline for another 12 weeks to help you stay cigarette-free.

If you are motivated to quit smoking and did not succeed during prior varenicline treatment for reasons other than side effects, or if you returned to smoking after treatment, speak with your healthcare provider about whether another course of varenicline therapy may be right for you.

 [Detailed Varenicline dosage information](#)

What happens if I miss a dose?

If you miss a dose of varenicline, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Just take your next dose at your regular time.

What should I avoid while taking varenicline?

Use caution when driving or operating machinery until you know how varenicline affects you. Varenicline may make you feel sleepy, dizzy, or have trouble concentrating, making it hard to drive or perform other activities safely.

Decrease the amount of alcoholic beverages that you drink during treatment with varenicline until you know if varenicline affects your ability to tolerate alcohol. Some people have experienced the following when drinking alcohol during treatment with varenicline:

- increased drunkenness (intoxication)
- unusual or sometimes aggressive behavior
- no memory of things that have happened.

What other drugs will affect varenicline?

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider may need to change the dose of some of your medicines when you stop smoking.

- You should not use varenicline while using other medicines to quit smoking. Tell your healthcare provider if you use other treatments to quit smoking.
- **Interaction with Alcohol:** Increased effects of alcohol have been reported. Instruct patients to reduce the amount of alcohol they consume until they know whether varenicline affects them.
- Using varenicline with a nicotine patch may cause nausea, vomiting, headache, dizziness, upset stomach, and tiredness to happen more often than if you just use a nicotine patch alone.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

 [Varenicline drug interactions](#) (more detail)

Does varenicline interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

varenicline

+

Enter a drug name

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Storage

Store at room temperature, between 68°F to 77°F (20°C to 25°C).

Keep out of the reach of children.

Generic varenicline ingredients

All generic varenicline tablets contain varenicline tartrate as the active ingredient but inactive ingredients may vary depending on the manufacturer. An example is given for Par Pharmaceuticals generic varenicline.

Par Pharmaceuticals generic varenicline

Active ingredient: varenicline tartrate 0.5 mg.

Inactive ingredients: croscarmellose sodium, maltodextrin, microcrystalline cellulose, stearic acid, hydroxypropyl cellulose (unspecified), hypromellose, talc, and titanium dioxide.

Active ingredient: varenicline tartrate 1 mg

Inactive ingredients: croscarmellose sodium, maltodextrin, microcrystalline cellulose, stearic acid, hydroxypropyl cellulose (unspecified), hypromellose, talc, titanium dioxide, FD&C Blue No. 2, Ferric Oxide Yellow.

Who makes varenicline?

Varenicline is made by various generic manufacturers including Apotex corp, Endo USA Inc., Par Pharmaceuticals, and Ascen Laboratories.

Popular FAQ

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References

1. [Varenicline package insert](#). Endo USA Ltd.

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Patient resources

- [Varenicline \(Nasal\) advanced reading](#)
- [Varenicline \(Oral\) \(Advanced Reading\)](#)

Other brands

[Chantix](#), [Tyrvaya](#)

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- [Varenicline Tartrate \(EENT\) monograph](#)
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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only

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 Risk data available

CSA Schedule*

N/A Not a controlled drug



Approval History

 Drug history at FDA



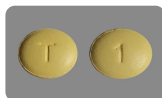
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