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MEDICATION GUIDE
Varenicline Tablets
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What is the most important information I should know about varenicline tablets?

When you try to quit smoking, with or without varenicline tablets, 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
- increased appetite
- 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.

Some people have had serious side effects while taking varenicline tablets to help them quit smoking, including:

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 tablets, and others developed them after several weeks of treatment, or after stopping varenicline tablets. These symptoms happened more often in people who had a history of mental health problems before taking varenicline tablets, than in people without a history of mental health problems.

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

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

What are varenicline tablets?

Varenicline tablets are a prescription medicine to help people 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.

Varenicline tablets have not been shown to be effective in children 16 years of age and under. Varenicline tablets should not be used in children 16 years of age and under.

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

Who should not take varenicline tablets?

Do not take varenicline tablets if you have had a serious allergic or skin reaction to varenicline 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

What should I tell my healthcare provider before taking varenicline tablets?

See "What is the most important information I should know about varenicline tablets?"

Before you take varenicline tablets, tell your healthcare provider if you:

- use other treatments to quit smoking. Using varenicline tablets 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 tablets for you.
- have a history of seizures
- drink alcohol
- have heart or blood vessel problems
- have any other medical conditions
- are pregnant or plan to become pregnant.
- are breastfeeding. It is not known if varenicline tablets passes into breast milk. If you breastfeed and take varenicline tablets, monitor your baby for seizures as well as spitting up or vomiting more than normal.

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 tablets while using other medicines to quit smoking. Tell your healthcare provider if you use other treatments to quit smoking.

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.

How should I take varenicline tablets?

- There are 3 ways that you can use varenicline tablets to help you quit smoking. Talk to your healthcare provider about the following 3 ways to use varenicline tablets:
  - Choose a **quit date** when you will stop smoking. Start taking varenicline tablets 1 week (7 days) before your **quit date**. Take varenicline tablets for 12 weeks.

    OR
  - Start taking varenicline tablets before you choose a **quit date**. Pick a date to quit smoking that is between days 8 and 35 of treatment. Take varenicline tablets for 12 weeks.

    OR
  - If you are sure that you are not able or willing to quit smoking right away, start taking varenicline tablets and reduce smoking during the first 12 weeks of treatment, as follows

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 tablets for another 12 weeks, for a total of 24 weeks of treatment.

Starting varenicline tablets before your **quit date** gives varenicline tablets time to build up in your body. You can keep smoking during this time. Take varenicline tablets exactly as prescribed by your healthcare provider.

- Varenicline tablets come as a white to off-white tablet (0.5 mg) and a white to off-white tablet (1 mg). You start with the white to off-white tablet (0.5 mg) and then usually go to the white to off-white (1 mg) tablet. See the chart below for dosing instructions for adults.

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

- Make sure that you try to stop smoking on your quit date. If you slip-up and smoke, try again. Some people need to take varenicline tablets for a few weeks for varenicline tablets to work best.
- Most people will take varenicline tablets for up to 12 weeks. If you have completely quit smoking by 12 weeks, your healthcare provider may prescribe varenicline tablets for another 12 weeks to help you stay cigarette-free.
- Take varenicline tablets after eating and with a full glass (8 ounces) of water.
- This dosing schedule 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.
- If you miss a dose of varenicline tablets, 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 tablets?

- Use caution when driving or operating machinery until you know how varenicline tablets affect you. Varenicline tablets 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 tablets until you know if varenicline tablets affect your ability to tolerate alcohol. Some people have experienced the following when drinking alcohol during treatment with varenicline tablets:
  - increased drunkenness (intoxication)
  - unusual or sometimes aggressive behavior
  - no memory of things that have happened

What are the possible side effects of varenicline tablets?

Serious side effects of varenicline tablets may include:

- **See "What is the most important information I should know about varenicline tablets?"**
- **Seizures.** Some people have had seizures during treatment with varenicline tablets. In most cases, the seizures have happened during the first month of treatment with varenicline tablets. If you have a seizure during treatment with varenicline tablets, stop taking varenicline tablets 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 tablets.

  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 feeling lightheaded associated with chest discomfort
- **Sleepwalking** can happen with varenicline tablets, and can sometimes lead to behavior that is harmful to you or other people, or to property. Stop taking varenicline tablets and tell your healthcare provider if you start sleepwalking.
- **Allergic reactions** can happen with varenicline tablets. 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 tablets 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

The most common side effects of varenicline tablets include:

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

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

These are not all the side effects of varenicline tablets. Ask your healthcare provider 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 varenicline tablets?

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

Keep varenicline tablets and all medicines out of the reach of children.

General information about the safe and effective use of varenicline tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use varenicline tablets for a condition for which it was not prescribed. Do not give your varenicline tablets to other people, even if they have the same symptoms that you have. They may harm them. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about varenicline tablets that is written for healthcare professionals.

For more information about varenicline tablets and tips on how to quit smoking, go to https://www.umedicalabs.com/varenicline.html or call 1-855-288-5777.

If you are motivated to quit smoking and did not succeed during prior varenicline tablets 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 tablets therapy may be right for you.

What are the ingredients in varenicline tablets?

Active ingredient: varenicline tartrate

Inactive ingredients: anhydrous dibasic calcium phosphate, colloidal silicon dioxide, magnesium stearate and microcrystalline cellulose.

Manufactured by:
Umedica Laboratories Pvt. Ltd.
Vapi, Gujarat 396195, INDIA.

Distributed by:
Umedica Laboratories USA Inc.
Parsippany, NJ, 07054.

Product of India

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