What is this medicine?

VARENICLINE (var EN i kleen) is used to help people quit smoking. It can reduce the symptoms caused by stopping smoking. It is used with a patient support program recommended by your physician.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

You should set a date to stop smoking and tell your doctor. Start this medicine one week before the quit date. You can also start taking this medicine before you choose a quit date, and then pick a quit date that is between 8 and 35 days of treatment with this medicine. Stick to your plan; ask about support groups or other ways to help you remain a ‘quitter’.

Take this medicine by mouth after eating. Take with a full glass of water. Follow the directions on the prescription label. Take your doses at regular intervals. Do not take your medicine more often than directed.

A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time.

Talk to your pediatrician regarding the use of this medicine in children. This medicine is not approved for use in children.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:

- Bipolar disorder, depression, schizophrenia or other mental illness
- Heart disease
- Kidney disease
- Peripheral vascular disease
- Stroke
- Suicidal thoughts, plans, or attempt; a previous suicide attempt by you or a family member
- An unusual or allergic reaction to varenicline, other medicines, foods, dyes, or preservatives
- Pregnant or trying to get pregnant
- Breast-feeding

What may interact with this medicine?

- Insulin
- Other stop smoking aids
- Theophylline
- Warfarin

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:

- Allergic reactions like skin rash, itching or hives, swelling of the face, lips, tongue, or throat
- Breathing problems
- Changes in vision
- Chest pain or chest tightness
- Confusion, trouble speaking or understanding
- Fast, irregular heartbeat
- Feeling faint or lightheaded, falls
- Fever
- Pain in legs when walking
- Problems with balance, talking, walking
- Ringing in ears
- Sudden numbness or weakness of the face, arm or leg
- Suicidal thoughts or other mood changes
- Trouble passing urine or change in the amount of urine
- Unusual bleeding or bruising
- Unusually weak or tired

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):
- Constipation
- Headache
- Nausea, vomiting
- Strange dreams
- Stomach gas
- Trouble sleeping

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

Visit your doctor or health care professional for regular check ups. Ask for ongoing advice and encouragement from your doctor or healthcare professional, friends, and family to help you quit. If you smoke while on this medication, quit again.

Your mouth may get dry. Chewing sugarless gum or sucking hard candy, and drinking plenty of water may help. Contact your doctor if the problem does not go away or is severe.

You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this medicine affects you. Do not stand or sit up quickly, especially if you are an older patient. This reduces the risk of dizzy or fainting spells.

The use of this medicine may increase the chance of suicidal thoughts or actions. Pay special attention to how you are responding while on this medicine. Any worsening of mood, or thoughts of suicide or dying should be reported to your health care professional right away.

Where should I keep my medicine?

Keep out of the reach of children.

Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Throw away any unused medicine after the expiration date.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.