

FDA 101: Smoking Cessation Products

If you want to quit smoking, you'll need willpower—and perhaps the aid of a product that's intended to help you beat the addiction.

The Food and Drug Administration (FDA) has approved a variety of smoking cessation products. These include prescription medicines as well as over-the-counter (OTC) products such as skin patches, lozenges, and gum.

Smoking cessation products are regulated through FDA's Center for Drug Evaluation and Research, which ensures that the products are effective and that their benefits outweigh any known associated risks.

First, Learn About the Products

While these products are intended to help you quit smoking and improve your health, it's important to know how they work and what side effects they may cause.

For example, many approved smoking cessation products help users wean themselves from smoking by using specific amounts of nicotine, the drug present in the tobacco plant which is primarily responsible for people's addiction to tobacco products.

And, as is the case with other medications, there are risks and other considerations associated with the various products that consumers must weigh against the benefits.

Reading labels and talking to your pharmacist and other health care professionals are good initial steps to take when considering the use of smoking cessation products. You can



also check FDA's Web site for more information on each product at Drugs@FDA (www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name).

The Benefits of Stopping

Beating the addiction to smoking will bring you a multitude of benefits. Not only will you lower your risk of getting various cancers, including lung cancer, you'll also reduce your chances of suffering from heart disease, stroke, emphysema, and other serious diseases. Also, stopping will help prevent heart disease and lung cancer in people who are subjected to your second-hand smoke.

Although there are benefits to quitting at any age, it is important to quit as early in life as possible to avoid getting one of these serious illnesses caused by smoking.

Keep in mind that

- smoking kills 1,200 people every day in the United States

- if you do not quit smoking, you have a one out of two chance of dying of a smoking-related disease

Nicotine Replacement Products

Nicotine replacement products are one type of smoking cessation product. Designed to wean your body off cigarettes, they supply you with nicotine in controlled amounts while sparing you from other chemicals found in tobacco products.

As you go about quitting smoking, you may experience symptoms of nicotine craving and withdrawal. These symptoms—which include an urge to smoke, depression, trouble sleeping, irritability, anxiety, and increased appetite—may occur no matter which method of stopping you choose.

Available over the counter and by prescription, nicotine replacement products should be used for a short time to help you deal with nicotine craving and withdrawal.

If you are under 18 years of age and

want to quit smoking, you should talk to a health care professional about the potential for using nicotine replacement therapies.

OTC nicotine replacement products are sold under brand names and private labels, and as generic products. They are approved for sale to persons 18 years of age and older.

OTC nicotine replacement products include

- **skin patches** available as generics known as transdermal nicotine patches, as private-label products, and under the brand names Habitrol and Nicoderm. These patches are affixed to the skin, similar to how you would apply an adhesive bandage
- **chewing gum** available as a generic product known as nicotine gum, as private-label products, and under the brand name Nicorette
- **lozenges** available as generics known as nicotine lozenges, as private-label products, and under the brand name Commit

Prescription-only nicotine replacement products are available only under the brand name Nicotrol and are available both as a nasal spray and an oral inhaler.

There is important advice to consider before beginning a nicotine replacement therapy.

- You should stop using a nicotine replacement product and call your health care professional if you experience nausea, dizziness, weakness, vomiting, fast or irregular heartbeat, mouth problems with the lozenge or gum, or redness or swelling of the skin around the patch that does not go away.
- Women who are pregnant or breastfeeding should use these products only with approval from their health care professional.
- Talk to your health care professional before using these products if you have
 - diabetes, heart disease, asthma, or stomach ulcers
 - had a recent heart attack

- high blood pressure that is not controlled with medicine
- a history of irregular heartbeat
- If you take prescription medication for depression or asthma, let your health care professional know if you are quitting smoking; your prescription dose may need to be adjusted.

Products Not Containing Nicotine

Two medicines that do not contain nicotine have FDA's approval as smoking cessation products. They are Chantix (varenicline tartrate) and Zyban (bupropion). Both are available in tablet form on a prescription-only basis.

In July 2009, FDA required both products to carry new safety information in a boxed warning on their labeling for health care professionals citing serious risks for users taking these drugs. These risks include changes in behavior, depressed mood, hostility, and suicidal thoughts or actions.

Read the product's patient medication guide in its entirety if you use or plan to use either Chantix or Zyban. These guides offer important information on adverse effects, risks, warnings, product ingredients, and what you should talk about with your health care professional before taking the products.

Chantix acts at sites in the brain affected by nicotine. It provides some nicotine effects to ease withdrawal symptoms and blocks the effects of nicotine from cigarettes if users resume smoking.

The medication guide for Chantix states that the product is not recommended for people under 18 years of age.

The most common side effects of Chantix include nausea; constipation; gas; vomiting; and trouble sleeping or vivid, unusual, or strange dreams.

In addition to the warnings about changes in behavior, depressed mood, hostility, and suicidal thoughts or actions when taking this drug, the patient medication guide for Chantix cites other adverse effects and risks—including allergic reactions, serious skin reactions, trouble driving or

operating heavy machinery, and new or worsening heart or blood vessel (cardiovascular) problems, mostly in people who already have cardiovascular problems.

Stop taking Chantix and call your health care professional right away if you notice any of these symptoms, or develop other symptoms included in the medication guide for patients. Patients should report side effects involving smoking cessation products to the FDA MedWatch program (<http://www.fda.gov/Safety/MedWatch/default.htm>).

Zyban helps patients to abstain from smoking; however, the precise means by which it accomplishes this is unknown.

The medication guide for Zyban states that the product has not been studied in children under the age of 18 and is not approved for use in children and teenagers.

The most commonly observed adverse events consistently associated with the use of Zyban are dry mouth and insomnia.

In addition to warnings about the risks of serious psychiatric problems, the medication guide for Zyban cites other adverse events and risks related to this product, including seizures, high blood pressure, and allergic reactions.

Since Zyban contains the same active ingredient as the antidepressant Wellbutrin, users and potential users are urged to talk to their health care professional about risks and benefits of treatment with antidepressant medicines. 

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