

FDA 101: Smoking Cessation Products

If you want to quit smoking, you'll need willpower—and perhaps 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 safe and 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 in the tobacco plant which is primarily responsible for people's addiction to tobacco products.

And, as is the case with all medications, consumers must weigh the benefits and risks as well as other considerations associated with the various products. 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

Overcoming the addiction to smoking will bring you a multitude of benefits. According to the National Institutes of Health (www.nhlbi.nih.gov/health/health-topics/topics/smo/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, quitting will help prevent heart disease and lung cancer in people who otherwise would be exposed 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 the serious illnesses caused by smoking.

Keep in mind that:

- according to the Centers for Disease Control and Prevention (www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/), more than 16 million Americans suffer from a disease caused by smoking
- if you do not quit smoking, you have a 50 percent chance of dying of a smoking-related disease

Nicotine Replacement Products

Nicotine replacement is one category 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 withdrawal. These symptoms—which include a craving, or 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 usually be used for a short time to help you manage nicotine cravings and withdrawal. However, FDA recognizes that some people may find that they need to use these products longer to stay smoke-free. FDA has determined that there do not appear to be significant safety concerns if smokers use nicotine replacement products in combination with another product, for example, a long-acting skin patch with a short-acting gum or if they do not stop smoking completely before beginning to use such products. You may want to talk with your health care professional to find your best

strategy to quit.

If you are under 18 years of age and want to quit smoking, you should talk to a health care professional about potential use of nicotine replacement therapies.

OTC nicotine replacement products are approved for sale to persons 18 years of age and older. These products are available under brand names and sometimes as generic products. They include:

- **skin patches** known as transdermal nicotine patches. These patches are affixed to the skin, similar to how you would apply an adhesive bandage.
- **chewing gum** also known as nicotine gum.
- **lozenges** also known as nicotine lozenges. Lozenges are taken by dissolving in the mouth.

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.

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
- been prescribed medication to help you quit smoking

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.

Stop using a nicotine replacement product and call your health care

professional if you experience any of the following symptoms: 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.

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 hydrochloride). Both are available in tablet form on a prescription-only basis. As with other prescription products, FDA has evaluated these and found that the benefits outweigh the risks. For users taking these products, risks include changes in behavior, depressed mood, hostility, aggression, 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. The most common side effects of Chantix include nausea; constipation; gas; vomiting; and trouble sleeping or vivid, unusual, or strange dreams.

It is not recommended for people under 18 years of age.

In addition to the warnings about changes in behavior, depressed mood, hostility, aggression, 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; seizures, and new or worsening heart or blood vessel (cardiovascular) problems, mostly in people who already have cardiovascular problems. Chantix may change

how you react to alcohol, and you should drink less alcohol until you know whether Chantix affects your tolerance for alcohol.

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.

The precise means by which Zyban aids smoking cessation is unknown.

Zyban 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 changes in behavior, hostility, agitation, depression and suicidal thoughts or actions while taking this drug, the medication guide for Zyban cites other adverse events and risks related to this product, including seizures, high blood pressure, and allergic reactions.

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

Patients should report side effects involving any smoking cessation products to the FDA MedWatch program (www.fda.gov/Safety/MedWatch/default.htm).

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