

Nicotine Replacement Therapy Labels May Change

When nicotine replacement therapy (NRT) products were first marketed almost 30 years ago to help people stop smoking, there wasn't a lot of data available on how long consumers could safely use them, and whether they could be used in combination with other NRTs or continued smoking.

That has changed in the intervening years as researchers conducted studies and clinical trials.

Now, the Food and Drug Administration—after reviewing scientific research on the safety of NRT products sold over the counter (OTC)—has decided that some warnings and limitations specified in the directions for use on the labels of these products are no longer necessary to make sure they are used safely and effectively to quit smoking.

The changes that FDA is allowing to these labels reflect the fact that although any nicotine-containing product is potentially addictive, decades of research and use have shown that NRT products sold OTC do not appear to have significant potential for abuse or dependence.

The changes being recommended by FDA include a removal of the warning that consumers should not use an NRT product if they are still smoking, chewing tobacco, using snuff or any other product that contains nicotine—including another NRT.



Patients should consult with their health care professional to select the most appropriate smoking cessation method to suit their needs, and to discuss any questions about the use of OTC nicotine replacement products. FDA has not seen evidence to support the statement that these products are safe for all smokers.

NRTs are FDA-approved for adults ages 18 and over who want to quit smoking. Smokers' dependence on nicotine prevents many who try to quit from being successful, and these products supply controlled amounts of nicotine to ease withdrawal symptoms.

"The agency heard from several public health groups that the labeling for OTC NRT products may stop consumers who are trying to quit smoking from using them," says FDA Com-

missioner Margaret A. Hamburg, M.D. "FDA hopes the recommended changes will allow more people to use these products effectively for smoking cessation and that tobacco dependence will decline in this country."

NRT Products Come in Three Forms

Tobacco product use is the leading preventable cause of death in the United States, responsible for

more than 440,000 deaths each year. Smoking causes multiple cancers, heart disease, stroke, complications of pregnancy, chronic obstructive pulmonary disease, and many other diseases that, on average, shorten a smoker’s lifespan by 14 years.

“One of the ways FDA works to reduce tobacco-related death and disease is to review and approve safe, effective therapies for consumers trying to quit smoking,” says Janet Woodcock, M.D., director of FDA’s Center for Drug Evaluation and Research (CDER). About 70 percent of smokers want to stop smoking, and nearly half of all smokers make an attempt to quit each year.

Several types of FDA-approved smoking cessation products are available, both with and without a prescription. Three types of NRT are approved by FDA for consumers to buy OTC: nicotine gum, transdermal nicotine patch, and nicotine lozenge products.

FDA first approved nicotine gum and patches as prescription products between 1984 and 1992. These products were shown to be safe and effective for use when someone first stops using cigarettes, and then uses the NRT to help manage the symptoms of withdrawal, usually for 8-12 weeks depending on the product.

The NRT gum and patch products were switched to OTC marketing between 1996 and 2002, based on scientific research showing that these products were safe for use without a prescription. The nicotine lozenge and mini-lozenge were approved directly for OTC use in 2002 and 2009, respectively.

FDA is allowing the companies who make these OTC products to make several changes to the warnings and limitations in the directions for use on their labels to allow some flexibility on how they are used and for how long. These changes mean the following for consumers:

- There are no significant safety concerns associated with using more than one OTC NRT at the

Current Drug Facts Labeling	Proposed Drug Facts Labeling
Warnings:	
<p>Do not use</p> <ul style="list-style-type: none"> • if you continue to smoke, chew tobacco, use snuff, or use [a different NRT product] or other nicotine containing products 	None. The “Do not use” statement would be deleted.
Directions:	
<ul style="list-style-type: none"> • stop smoking completely when you begin using the [NRT product] 	<ul style="list-style-type: none"> • begin using [the NRT product] on your quit day
<ul style="list-style-type: none"> • it is important to complete treatment. Stop using [the NRT product] at the end of [a specified number of] weeks. If you still feel the need to use [the NRT product], talk to your doctor 	<ul style="list-style-type: none"> • it is important to complete treatment. If you feel you need to use [the NRT product] for a longer period to keep from smoking, talk to your health care provider

same time, or using an OTC NRT at the same time as another nicotine-containing product—including a cigarette. If you are using an OTC NRT while trying to quit smoking but slip up and have a cigarette, you should not stop using the NRT. You should keep using the OTC NRT and keep trying to quit.

- NRT users should still pick a day to quit smoking, and begin using the OTC NRT product on their “quit” day, even if they aren’t immediately able to stop smoking.
- Users of NRT products should still use the product for the length of time indicated in the label—for example, 8, 10 or 12 weeks. However, if they feel they need to continue using the product for longer in order to quit, it is safe to do so in most cases. Consumers are advised to consult their health care professional if they feel the need to use an OTC NRT for longer than the time period recommended in the label.

The labeling for OTC NRTs may not change immediately, so consumers should:

- Make sure to read the packaging and labeling of any NRT product you purchase;
- Talk to your health care professional if you are thinking about quitting smoking and have questions or concerns about NRT. Your health care professional is also the expert to consult with questions about an NRT you are currently using.
- Report side effects involving an OTC NRT to the FDA MedWatch Reporting Program at: <http://www.fda.gov/Safety/MedWatch/default.htm>.

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