

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 74-707**

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# **Nicotine Polacrilex Gum USP, 4 mg (nicotine)**

**Nicotine Polacrilex Gum Usage Instructions**

**HOW TO USE  
NICOTINE POLACRILEX GUM  
TO HELP YOU QUIT SMOKING**

© 1999 Watson Laboratories, Inc.

### **KEYS TO SUCCESS.**

- **NOT for sale to those under 18 years of age.**
- **Proof of age required.**
- **Not for sale in vending machines or from any source where proof of age cannot be verified.**

- 1) You must really want to quit smoking for **Nicotine Polacrilex Gum** to help you.
- 2) You can greatly increase your chances for success by using at least 9 to 12 pieces every day when you start using **Nicotine Polacrilex Gum**. (See page 10)
- 3) You should continue to use **Nicotine Polacrilex Gum** as explained in this User's Guide for 12 full weeks.
- 4) **Nicotine Polacrilex Gum** works best when used together with a support program. (See page 3)
- 5) If you have trouble using **Nicotine Polacrilex Gum**, ask your doctor or pharmacist, or call Watson at 1-877-JUS-STOP.



**SO YOU DECIDED TO QUIT.** Congratulations. Your decision to stop smoking is an important one. That's why you've made the right choice in choosing Nicotine Polacrilex Gum (pronounced "nik'-ah-teen poh-lah-cry'-lex gum").

Your own chances of quitting smoking depend on how much you want to quit, how strongly you are addicted to tobacco,

and how closely you follow a quitting program like the one that comes with Nicotine Polacrilex Gum.

**QUITTING SMOKING IS HARD!** If you've tried to quit before and haven't succeeded, don't be discouraged! Quitting

isn't easy. It takes time, and most people try a few times before they are successful. The important thing is to

try again until you succeed. This User's Guide will give you support as you become a non-smoker. It will answer common questions about Nicotine Polacrilex Gum and give tips to help you stop smoking, and should be referred to often.

**WHERE TO GET HELP.** You are more likely to stop smoking by using Nicotine Polacrilex Gum with a support program that helps you break your smoking habit. There may be support groups in your area for people trying to quit. Call your local chapter of the American Lung Association, American Cancer Society or American Heart Association for further information. Toll free numbers are printed on the Wallet Card on the back cover of this User's Guide.

If you find you cannot stop smoking or if you start smoking again after using Nicotine Polacrilex Gum, remember breaking this addiction doesn't happen overnight. You may want to talk to a health care professional who can help you improve your chances of quitting the next time you try Nicotine Polacrilex Gum or another method.

**LET'S GET ORGANIZED.** Your reason for quitting may be a combination of concerns about health, the effect of smoking on your appearance, and pressure from your family and friends to stop smoking. Or maybe you're concerned about the dangerous effect of second-hand smoke on the people you care about.

All of these are good reasons. You probably have others. Decide your most important reasons, and write them down on the wallet card inside the back cover of this User's Guide. Carry this card with you. In difficult moments, when you want to smoke, the card will remind you why you are quitting.

**WHAT YOU'RE UP AGAINST.** Smoking is addictive in two ways. Your need for nicotine has become both physical and mental. You must overcome both addictions to stop smoking. So while Nicotine Polacrilex Gum will lessen your body's physical addiction to nicotine, you've got to want to quit smoking to overcome the mental dependence on cigarettes. Once you've decided that you're going to quit, it's

time to get started. But first, there are some important cautions you should consider.

**SOME IMPORTANT CAUTIONS.** This product is only for those who want to stop smoking.

Do not smoke, chew tobacco, use snuff or nicotine patches while using Nicotine Polacrilex Gum.

If you have heart disease, a recent heart attack, irregular heartbeats, palpitations, high blood pressure not controlled with medication, stomach ulcer, or take insulin for diabetes, ask your doctor whether you should use Nicotine Polacrilex Gum.

As with any drug, if you are pregnant or nursing a baby, seek the advice of

a health professional before using this product.

If you take a prescription medication for asthma or depression, be sure your doctor knows you are quitting smoking. Your prescription medication dose may need to be adjusted.

Those under 18 should use this product under a doctor's care.

Symptoms of nicotine overdose may include vomiting and diarrhea. Young children are more likely to have additional symptoms, including weakness. Also, seizures have been seen in children who swallowed cigarettes.

Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

**LET'S GET STARTED.** Becoming a non-smoker starts today. Your first step is to read through this entire User's Guide carefully.

Next, set your personalized quitting schedule.

Take out a calendar that you can use to track your progress, and identify four dates, using the stickers in the center of this User's Guide:

**STEP 1. Your quit date (and the day you'll start using Nicotine Polacrilex Gum).**

Choose your quit date (it should be soon). This is the day you will quit smoking cigarettes entirely and begin using Nicotine Polacrilex Gum to satisfy your cravings for nicotine. For the first six weeks, you'll use a

piece of Nicotine Polacrilex Gum every hour or two. Be sure to follow the directions. Place the Step 1 sticker on this date.

**STEP 2.** The day you'll start reducing your use of Nicotine Polacrilex Gum. After six weeks, you'll begin gradually reducing your Nicotine Polacrilex Gum usage to one piece every two to four hours. Place the Step 2 sticker on this date (the first day of week seven).

**STEP 3.** The day you'll further reduce your use of Nicotine Polacrilex Gum. Nine weeks after you begin using Nicotine Polacrilex Gum, you will further reduce your nicotine intake by using one piece every four to eight hours. Place the Step 3 sticker on this date (the first day of week ten). For the next three weeks, you'll use a piece of

Nicotine Polacrilex Gum every four to eight hours.

**End of treatment:** The day you'll complete Nicotine Polacrilex Gum therapy. Nicotine Polacrilex Gum should not be used for longer than twelve weeks. Identify the date thirteen weeks after the date you choose in Step 1, and place the "EX-SMOKER" sticker on your calendar.

**PLAN AHEAD.** Because smoking is an addiction, it is not easy to stop. After you've given up cigarettes, you will still have a strong urge to smoke. Plan ahead NOW for these times, so you're not defeated in a moment of weakness. The following tips may help:

- Keep the phone numbers of supportive friends and family members handy.
- Keep a record of your quitting process. Track the number of Nicotine Polacrilex Gum pieces you use each day, and whether you feel a craving for cigarettes. If you smoke at all, write down what you think caused the slip.
- Put together an Emergency Kit that includes items that will help take your mind off occasional urges to smoke. Include cinnamon gum or lemon drops to suck on, a relaxing cassette tape, and something for your hands to play with, like a smooth rock, rubber band, or small metal balls.
- Set aside some small rewards, like a new magazine or a gift certificate

from your favorite store, which you'll "give" yourself after passing difficult hurdles.

- Think now about the times when you most often want a cigarette, and then plan what else you might do instead of smoking. For instance, you might plan to take your coffee break in a new location, or take a walk right after dinner, so you won't be tempted to smoke.

**HOW NICOTINE POLACRILEX GUM WORKS.** Nicotine Polacrilex Gum sugar-free chewing pieces provide nicotine to your system—they work as

a temporary aid to help you quit smoking by reducing nicotine withdrawal

symptoms. Nicotine Polacrilex Gum provides a lower level of nicotine to your blood than cigarettes, and allows you to gradually do away with your body's need for nicotine.

Because Nicotine Polacrilex Gum does not contain the tar or carbon monoxide of cigarette smoke, it does not have the same health dangers as tobacco. However, it still delivers nicotine, the addictive part of cigarette smoke. Nicotine can cause side effects such as headache, nausea, upset stomach, and dizziness.

## **HOW TO USE** **NICOTINE** **POLACRILEX** **GUM.**

Before you can use Nicotine Polacrilex Gum correctly, you have to practice! That sounds silly, but it isn't. Nicotine Polacrilex Gum isn't like ordinary chewing gum. It's a medicine, and must be chewed a certain way to work right. Chewed like ordinary gum, Nicotine Polacrilex Gum won't work well and can cause side effects. An overdose can occur if you chew more than one piece of Nicotine Polacrilex Gum at the same time, or if you chew many pieces one after another. Read all the following instructions before using Nicotine Polacrilex Gum. Refer to them often to make sure you're using

Nicotine Polacrilex Gum correctly. If you chew too fast, or do not chew correctly, you may get hiccups, heartburn, or other stomach problems.

- 1) Stop smoking completely before you start using Nicotine Polacrilex Gum.
- 2) To reduce craving and other withdrawal symptoms, use Nicotine Polacrilex Gum according to the dosage schedule. (See page 10)
- 3) Chew each Nicotine Polacrilex Gum piece very slowly several times.
- 4) Stop chewing when you notice a peppery taste, or a slight tingling in your mouth. (This usually happens after about 15 chews, but may vary from person to person.)
- 5) "PARK" the Nicotine Polacrilex Gum piece between your cheek and gum, and leave it there.
- 6) When the peppery taste or tingle is almost gone (in about a minute), start to chew a few times slowly again. When the taste or tingle returns, stop again.
- 7) Park the Nicotine Polacrilex Gum piece again (in a different place in your mouth).
- 8) Repeat steps 3 to 7 (chew, chew, park) until most of the nicotine is gone from the Nicotine Polacrilex Gum piece (usually happens in about half an hour; the peppery taste or tingle won't return.)
- 9) Throw away the used Nicotine Polacrilex Gum piece - safely away from children and pets.

**THE FOLLOWING CHART LISTS THE RECOMMENDED USAGE SCHEDULE FOR NICOTINE POLACRILEX GUM:**

Weeks 1 through 6	Weeks 7 through 9	Weeks 10 through 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours
<b>DO NOT USE MORE THAN 24 PIECES PER DAY.</b>		

To improve your chances of quitting, use at least 9 pieces of Nicotine Polacrilex Gum a day. Heavier smokers may need more pieces to reduce their cravings.

Don't eat or drink for 15 minutes before using Nicotine Polacrilex Gum, or while chewing a piece. The effectiveness of Nicotine Polacrilex Gum may be reduced by some foods and drinks, such as coffee, juices, wine or soft drinks.

**HOW TO REDUCE YOUR NICOTINE POLACRILEX GUM USAGE.** The goal of using Nicotine Polacrilex Gum is to slowly reduce your dependence on nicotine. The schedule for using Nicotine Polacrilex Gum will help you reduce your nicotine craving gradually. Here are some tips to help you cut back during each step:

**PLACE THESE STICKERS ON YOUR CALENDAR:**



AT THE BEGINNING OF WEEK #1  
(QUIT DATE)

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AT THE BEGINNING OF WEEK #7

**PLACE THESE STICKERS ON YOUR CALENDAR:**



AT THE BEGINNING OF WEEK #10

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12 WEEKS AFTER QUIT DATE

- After a while, start chewing each Nicotine Polacrilex Gum piece for only 10 to 15 minutes, instead of half an hour. Then, gradually begin to reduce the number of pieces used.
- Or, try chewing each piece for longer than half an hour, but reduce the number of pieces you use each day.
- Substitute ordinary chewing gum for some of the Nicotine Polacrilex Gum pieces you would normally use. Increase the number of pieces of ordinary gum as you cut back on the Nicotine Polacrilex Gum pieces.

**STOP USING NICOTINE POLACRILEX GUM AT THE END OF WEEK 12.** If you still feel the need to use Nicotine Polacrilex Gum after Week 12, talk with your doctor.

**TIPS TO MAKE QUITTING EASIER.** Within the first few weeks of giving up smoking, you may be tempted to smoke for pleasure, particularly after completing a difficult task, or at a party or bar. Here are some tips to help get you through the important first stages of becoming a non-smoker:

**On Your Quit Date:**

- Ask your family, friends and co-workers to support you in your efforts to stop smoking.
- Throw away all your cigarettes, matches, lighters, ashtrays, etc.
- Keep busy on your quit day. Exercise. Go to a movie. Take a walk. Get together with friends.

- Figure out how much money you'll save by not smoking. Most ex-smokers can save more than \$1,000 a year.
- Write down what you will do with the money you save.
- Know your high risk situations and plan ahead how you will deal with them.
- Keep Nicotine Polacrilex Gum near your bed, so you'll be prepared for any nicotine cravings when you wake up in the morning.
- Visit your dentist and have your teeth cleaned to get rid of the tobacco stains.

**Right after Quitting:**

- During the first few days after you've stopped smoking, spend as much time as possible at places where smoking is not allowed.



- Drink large quantities of water and fruit juices.
- Try to avoid alcohol, coffee and other beverages you associate with smoking.

- Remember that temporary urges to smoke will pass, even if you don't smoke a cigarette.
- Keep your hands busy with something like a pencil or a paper clip.
- Find other activities which help you relax without cigarettes. Swim, jog, take a walk, play basketball.
- Don't worry too much about gaining weight. Watch what you eat, take time for daily exercise, and change your eating habits if you need to.



- Laughter helps. Watch or read something funny.

**WHAT TO EXPECT.** Your body is now coming back into balance. During the first few days after you stop smoking, you might feel edgy and nervous and have trouble concentrating. You might get headaches, feel dizzy and a little out of sorts, feel sweaty or have stomach upsets. You might even have trouble sleeping at first. These are typical withdrawal symptoms that will go away with time. Your smoker's cough will get worse before it gets better. But don't worry, that's a good sign. Coughing helps clear the tar deposits out of your lungs.

#### After A Week Or Two.

By now you should be feeling more confident that you can handle those smoking urges. Many of your withdrawal symptoms have left by now, and you should be noticing some positive signs: less coughing, better breathing and an improved sense of taste and smell, to name a few.

#### After A Month.

You probably have the urge to smoke much less often now. But urges may still occur, and when they do, they are likely to be powerful ones that come out of nowhere. Don't let them catch you off guard. Plan ahead for these difficult times.

Concentrate on the ways non-smokers are more attractive than smokers. Their skin is less likely to wrinkle. Their teeth

are whiter, cleaner. Their breath is fresher. Their hair and clothes smell better. That cough that seems to make even a laugh sound more like a rattle is a thing of the past. Their children and others around them are healthier, too.

#### What To Do About Relapse.

What should you do if you slip and start smoking again? The answer is simple. A lapse of one or two or even a few cigarettes has not spoiled your efforts! Discard your cigarettes, forgive yourself and try again.

If you start smoking again, keep your box of Nicotine Polacrilex Gum for your next quit attempt.

If you have taken up regular smoking again, don't be discouraged. Research shows that the best thing you can do is to try again. The important thing is to learn from your last attempt.

- Admit that you've slipped, but don't treat yourself as a failure.
- Try to identify the "trigger" that caused you to slip, and prepare a better plan for dealing with this problem next time.
- Talk positively to yourself - tell yourself that you have learned something from this experience.
- Make sure you used Nicotine Polacrilex Gum correctly over the full 12 weeks to reduce your craving for nicotine.

- Remember that it takes practice to do anything, and quitting smoking is no exception.

#### WHEN THE STRUGGLE IS OVER.

Once you've stopped smoking, take a second and pat yourself on your back. Now do it again. You deserve it.

Remember now why you decided to stop smoking in the first place. Look at your list of reasons. Read them again. And smile.

Now think about all the money you are saving and what you'll do with it. All the non-smoking places you can go, and what you might do there. All those years you may have added to your life, and what you'll do with them.

Remember that temptation may not be gone forever. However, the hard part is behind you so look forward with a positive attitude, and enjoy your new life as a non-smoker.

## QUESTIONS & ANSWERS.

### 1. How will I feel when I stop smoking and start using Nicotine Polacrilex Gum?

You'll need to prepare yourself for some nicotine withdrawal symptoms. These begin almost immediately after you stop smoking, and are usually at their worst during the first three or four days. Understand that any of the following is possible:

- craving for cigarettes
- anxiety, irritability, restlessness, mood changes, nervousness
- drowsiness
- trouble concentrating
- increased appetite and weight gain
- headaches, muscular pain, constipation, fatigue.

Nicotine Polacrilex Gum can help provide relief from withdrawal symptoms such as irritability and nervousness, as well as the craving for nicotine you used to satisfy by having a cigarette.

### 2. Is Nicotine Polacrilex Gum just substituting one form of nicotine for another?

Nicotine Polacrilex Gum does contain nicotine. The purpose of Nicotine Polacrilex Gum is to provide you with enough nicotine to help control the physical withdrawal symptoms so you can deal with the mental aspects of quitting. During the 12 week program, you will gradually reduce your nicotine intake by switching to fewer pieces each day. Remember, don't use Nicotine Polacrilex Gum together with nicotine patches or other nicotine containing products.

### 3. Can I be hurt by using Nicotine Polacrilex Gum?

For most adults, the amount of nicotine in the gum is less than from smoking. Some people will be sensitive to even this amount of nicotine and should not use this product without advice from their doctor. (See page 4) Because Nicotine Polacrilex Gum is a gum-based product, chewing it can cause dental fillings to loosen and aggravate other mouth, tooth and jaw problems. Nicotine Polacrilex Gum can also cause hiccups, heartburn and other stomach problems especially if chewed too quickly or not chewed correctly.

**4. Will I gain weight?**

Many people do tend to gain a few pounds the first 8-10 weeks after they stop smoking. This is a very small price to pay for the enormous gains that you will make in your overall health and attractiveness. If you continue to gain weight after the first two months, try to analyze what you're doing differently. Reduce your fat intake, choose healthy snacks, and increase your physical activity to burn off the extra calories.

**5. Is Nicotine Polacrilex Gum more expensive than smoking?**

The total cost of Nicotine Polacrilex Gum for the 12 week program is about equal to what a person who smokes one and a half packs of cigarettes a day would spend on cigarettes for the same period of time. Also, use of Nicotine Polacrilex Gum is only a short-term cost, while the cost of smoking is a long-term cost, because of the health problems smoking causes.

**6. What if I slip up?**

Discard your cigarettes, forgive yourself and then get back on track. Don't consider yourself a failure or punish yourself. In fact, people who have already tried to quit are more likely to be successful the next time.

**GOOD LUCK!**



**RECOMMENDED DOSAGE SCHEDULE FOR  
NICOTINE POLACRILEX GUM:**

<b>STEP 1</b>	<b>STEP 2</b>	<b>STEP 3</b>
<b>Weeks 1 to 6</b>	<b>Weeks 7 to 9</b>	<b>Weeks 10 to 12</b>
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

**WALLET CARD**

**My most important reasons  
to quit smoking are:**

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**WALLET CARD**

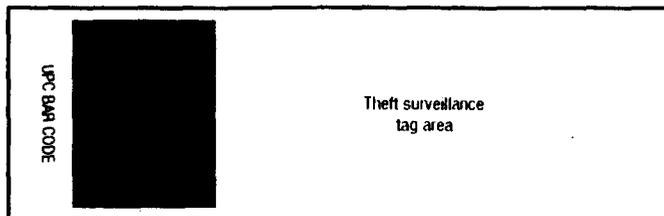
**Where to call for help:**

American Lung Association  
1-800-586-4872

American Cancer Society  
1-800-227-2345

American Heart Association  
1-800-242-8721





Top

**DIRECTIONS:**

- Stop smoking completely when you begin using Nicotine Polacrilex Gum.
- Read the enclosed User's Guide before using Nicotine Polacrilex Gum.
- Use Nicotine Polacrilex Gum as directed in the User's Guide.
- Do not eat or drink for 15 minutes before using Nicotine Polacrilex Gum or while chewing a piece.

• Use according to the following 12-week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- Do not exceed 24 pieces a day.
- Stop using Nicotine Polacrilex Gum at the end of week 12. If you still feel the need for Nicotine Polacrilex Gum, talk with your doctor.

Side

**REFILL**  
Refill for use with Nicotine Polacrilex Gum.

# Nicotine Polacrilex Gum USP, 4 mg (nicotine)

**STOP SMOKING AID**

- Nicotine medicine to help you stop smoking.
- Formerly available only by prescription.

**FOR SMOKERS OVER 24 CIGARETTES A DAY**  
IF YOU SMOKE LESS: Try Nicotine Polacrilex Gum USP, 2 mg

48 chewing pieces

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Front

1. Peel gum from the pack through the tear strip.

2. Peel backing away from the gum.

3. Remove the gum from the pack and use it.

**INACTIVE INGREDIENTS:** Butylated hydroxytoluene, carnauba wax, flavors, glycerin, gum base, sodium carbonate, sorbitol, and FD&C Yellow #6 Lake, FD&C Red #40 and FD&C Blue #2 Lake. Do not store above 86°F (30°C). Protect from light.

Manufactured by Watson Laboratories, Inc.  
Columbia, NY 11726

Comments or questions?  
Call 1-877-JUS-STOP

Blister recapped for your protection. Do not use if individual seals are broken.

Side

MAR 19 1999

Lot Number

Expiration Date

Bottom

**Nicotine Polacrilex Gum, USP**  
**Active Ingredient: nicotine 4 mg**

48 chewing pieces

**ACTION:** Stop Smoking Aid

**USE:** To reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking

**WARNINGS:**

- Keep this and all drugs out of reach of children and pets. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.
- Nicotine can increase your baby's heart rate; if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

**DO NOT USE IF YOU**

- Continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine-containing products.

**ASK YOUR DOCTOR BEFORE USE IF YOU**

- Are under 18 years of age.
- Have heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- Have high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- Have stomach ulcer or take insulin for diabetes.
- Take prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

**STOP USE AND SEE YOUR DOCTOR IF YOU HAVE**

- Mouth, teeth, or jaw problems.
- Irregular heartbeat, palpitations.
- Symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness, and rapid heartbeat.

- Not for sale to those under 18 years of age.

- Proof of age required.

- Not for sale in vending machines or from any source where proof of age cannot be verified.

**READ THE LABEL**

Read carton and enclosed User's Guide before taking this product. Do not discard carton or User's Guide. They contain important information.

Back

# Nicotine Polacrilex Gum, USP

**NICOTINE POLACRILEX GUM, USP**  
Active ingredient: nicotine 4 mg

**108 chewing pieces**

Top

**Nicotine Polacrilex  
Gum USP,  
4 mg (nicotine)**

Blister packaged for your  
protection. Do not use if individual  
seals are broken.

Expiration Date

Lot Number

Side

# Nicotine Polacrilex Gum USP, 4 mg (nicotine)

## STOP SMOKING AID

- Nicotine medicine to help you stop smoking.
- Formerly available only by prescription.

**FOR SMOKERS OVER 24 CIGARETTES A DAY**

**IF YOU SMOKE LESS:** Try Nicotine Polacrilex Gum USP, 2 mg

**108 chewing pieces**

1999 Watson Laboratories

## STARTER KIT

Includes stop smoking  
plan with User's Guide  
and audiotape

Front

**Nicotine Polacrilex  
Gum USP,  
4 mg (nicotine)**

Theft surveillance  
tag area



UPC BAR CODE

Side

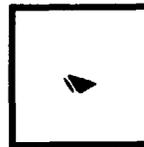
19 1999

### TO INCREASE YOUR SUCCESS IN QUITTING:

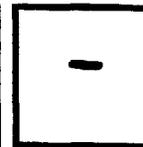
1. You must be motivated to quit.
2. **Use Enough** — Chew at least 9 pieces of Nicotine Polacrilex Gum per day during the first six weeks.
3. **Use Long Enough** — Use Nicotine Polacrilex Gum for the full 12 weeks.
4. **Use with a support program** as described in the enclosed User's Guide.



To remove the gum, tear off single unit.



Peel backing starting at corner with loose edge.



Push gum through foil.

Bottom

#### **ACTION:** Stop Smoking Aid

**USE:** To reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking.

#### **WARNINGS:**

- Keep this and all drugs out of reach of children and pets. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.
- Nicotine can increase your baby's heart rate; if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

#### **DO NOT USE IF YOU**

- Continue to smoke, chew tobacco, use snuff, or use a nicotine patch or other nicotine-containing products.

#### **ASK YOUR DOCTOR BEFORE USE IF YOU**

- Are under 18 years of age.
- Have heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- Have high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- Have stomach ulcer or take insulin for diabetes.
- Take prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

#### **STOP USE AND SEE YOUR DOCTOR IF YOU HAVE**

- Mouth, teeth, or jaw problems.
- Irregular heartbeat, palpitations.
- Symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat.

#### **READ THE LABEL**

Read carton and enclosed User's Guide before taking this product. Do not discard carton or User's Guide. They contain important information.

#### **DIRECTIONS:**

- Stop smoking completely when you begin using Nicotine Polacrilex Gum.
- Read the enclosed User's Guide before using Nicotine Polacrilex Gum.
- Use properly as directed in the User's Guide.
- Don't eat or drink for 15 minutes before using Nicotine Polacrilex Gum or while chewing a piece.
- Use according to the following 12-week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- Do not exceed 24 pieces a day.
- Stop using Nicotine Polacrilex Gum at the end of week 12. If you still feel the need for Nicotine Polacrilex Gum, talk with your doctor.

**INACTIVE INGREDIENTS:** Butylated hydroxytoluene, carnauba wax, flavors, glycerin, gum base, sodium carbonate, sorbitol, and FD&C Yellow #6 Lake, FD&C Red #40 and FD&C Blue #2 Lake. Do not store above 86°F (30°C). Protect from light.



Manufactured by Watson Laboratories, Inc.  
Copiague, NY 11726  
Comments or questions?  
Call 1-877-JUS-STOP

- Not for sale to those under 18 years of age.
- Proof of age required.
- Not for sale in vending machines or from any source where proof of age cannot be verified.

Back

**Nicotine Polacrilex Gum Audio Tape  
Side A, Section 1**

**SFX:** Sound of various voices from happy crowd.

**ANNCR:** Congratulations on your decision to become a non-smoker. This is one of the most important decisions you'll ever make. And one of the best.

**(VOICES:** "Yeah! Right! Way to go!")

The Nicotine Polacrilex Gum User's Guide and this audio tape are designed to help make it as easy as possible to break the habit. But keep in mind that this program won't work unless you're really committed to becoming a non-smoker. Maybe you tried before and failed. If so, don't be discouraged. Remember, lots of people make several tries before they succeed. This time, Nicotine Polacrilex Gum will help relieve the physical symptoms of quitting, so you are better equipped to manage the mental part.

**(VOICE:** "Yeah -- you can do it")

Even though Nicotine Polacrilex Gum is easy to use, it's not used like ordinary chewing gum. It's serious medicine! Like any medicine, you should use it only as directed. We'll get to the directions later, but you should also know that there are some people who shouldn't use Nicotine Polacrilex Gum or any product containing nicotine without checking with their doctor. Women who are pregnant or nursing, for example.

And anyone with a history of heart trouble, high blood pressure that can't be controlled with medication, takes insulin for diabetes or has a stomach ulcer should get medical advice first. Quitting smoking can also affect the way your body reacts to certain other medications you may be taking for asthma or depression -- so check with your doctor if any of these things apply to you.

Be sure to read the User's Guide that comes in this kit for other important information about using Nicotine Polacrilex Gum.

Even though Nicotine Polacrilex Gum contains nicotine, it doesn't contain any of the thousands of other harmful chemicals that are in cigarette smoke. And it's designed to get you off nicotine for good.

**Nicotine Polacrilex Gum audio tape**  
**Side A, Section 2**

*Support group. Adults. Group leader is authoritative but pleasant woman. Among students are Older Woman (OW), Young Woman (YW), Young Man (YM), and cynical Older Man with gruff voice (OM).*

(SFX: Murmurs, conversation. Leader raps on desk for attention.)

**LEADER:** All right; quiet now. This support group is all about how to use Nicotine Polacrilex Gum to help you quit smoking.

**OM:** So who needs a support group? It's a chewing gum. You chew it. We might as well have to take a class on how to breathe.

**LEADER:** How to Breathe is Mr. Yamato's group, down the hall. You'll be in that one later. But this comes first because Nicotine Polacrilex Gum isn't ordinary chewing gum. You have to use it the right way or it won't work the way it's supposed to.

**OM:** Hey, chewing gum is kid stuff.

**LEADER:** But chewing Nicotine Polacrilex Gum isn't. It's only for people who are at least 18 and really want to quit smoking. Younger people should talk to a doctor first.

Okay, let's begin. First, has everybody read the Nicotine Polacrilex Gum User's Guide?

**OW:** I read it. It didn't take long and it made the whole quitting process a lot clearer to me.

**LEADER:** There's nothing mysterious or complicated about it. But there's a right way to do it, and the only way you can expect to get the results you want is to use Nicotine Polacrilex Gum the way it's supposed to be used.

Now, who remembers the very first instruction?

**OW:** Buy Nicotine Polacrilex Gum?

**LEADER:** Actually, there's an even earlier step. Before using Nicotine Polacrilex Gum you have to stop smoking -- and I mean completely. That's important! And you mustn't chew tobacco or use snuff or nicotine patches either.

You start using Nicotine Polacrilex Gum on the day you stop smoking, and you never smoke and use Nicotine Polacrilex Gum together. That could give an overdose of nicotine, which is pretty powerful stuff. The results could make you sick.

**YW:** I know. Sometimes if I smoke two or three cigarettes in row, like if I'm nervous, I get dizzy.

**LEADER:** Sure. The next question is: when are you going to stop? Has everybody picked a Quit Date?

**OM:** Yeah, I have. I have to attend a seminar on Monday, in a nonsmoking building. I figure if Nicotine Polacrilex Gum can get me through the first day, it'll be easier from then on.

**LEADER:** Not a bad idea. Just be careful. When you walk out of the building, there's going to be a terrific desire to have a smoke, so you have to be prepared for that. The Nicotine Polacrilex Gum User's Guide includes a list of tips for handling those temptations. Anybody else?

**OW:** I'm going to quit as soon as possible. After I take today's classes I'm going to stop smoking. I already marked tomorrow on my calendar.

**LEADER:** That's it. Pick a date and stick with it. How about you, miss?

**YW:** My cousin is visiting this weekend. I figure I'll be so busy showing her around, I won't have time to think about wanting to smoke! And if I am tempted to slip, she could talk me out of it.

**LEADER:** Actually, the idea of having support when you need it is a good one. A friend or family member, maybe even a co-worker, can provide moral support. Several national organizations offer support groups like this one - there's a list of their toll-free phone numbers on the back cover of the Nicotine Polacrilex Gum User's Guide.

**YM:** So, the first step is to pick a Quit Date, and mark it in our calendar.

**LEADER:** Now, we have to learn how to use Nicotine Polacrilex Gum.

**OM:** What's the big deal about that?

**LEADER:** As I said before, Nicotine Polacrilex Gum isn't ordinary chewing gum, so you don't chew it the way you're used to. The big difference is that it contains nicotine, which you release by chewing it. The idea is to chew it so it releases the nicotine gradually -- not too fast, not too slow.

**OW:** I know -- it was in the book. You chew it until you get a tingling feeling in your mouth. Then you park it between your cheek and your gum until the tingling feeling goes away. You keep it there until you don't get anymore tingling.

**LEADER:** Right again. First you chew, then you park. Then you chew, then you park. You do that until the zing is gone. It takes about 15 chews to develop the tingling, and it takes a minute or so for it to go away. So the method is chew, park, chew, park. Let's all repeat that.

**CLASS:** (not quite together): Chew, park, chew, park, chew, park...

**LEADER:** Pretty good, but let's get it together a little bit better. One more time -- and a one, and a two and a...

**CLASS** (in unison): Chew, park, chew, park, chew, park, chew.

**LEADER:** Terrific!

**OM:** So when do we use this stuff? After meals, or what?

**LEADER:** The recommended schedule is a piece every hour or two while you're awake for the first six weeks. That's 8 to 16 pieces a day. You'll have the best chance of staying smoke-free if you use at least 9 pieces a day. Heavy smokers might need to go all the way up to 24 pieces a day.

**YM:** You mean if I start with 16 pieces a day, I have to use 16 pieces a day for six weeks?

**LEADER:** No. The idea is to cut down gradually on your body's need for nicotine. So if you start with 16 pieces a day, try to cut down after the first week to 14 pieces. After another week you may be able to cut down to 12. It would be ideal if you could get yourself down to 8 to 10 pieces a day by the end of the first six weeks.

**OW:** The book says to use a piece every two to four hours during weeks seven to nine. And the book also includes calendar stickers to mark week seven now, so we'll be reminded when to start decreasing the amount we use.

**LEADER:** Yes it does. Again, the idea is to start with the recommended dosage, and to decrease it gradually, at a rate you feel comfortable with. Then, for the last three weeks -- weeks 10 through 12 -- you should be able to get along with a piece every 4 to 8 hours. At the end of the 12 weeks you shouldn't need Nicotine Polacrilex Gum any longer.

**YW:** It sounds pretty easy. Anything else we should know?

**LEADER:** Well, if you have kids or pets at home make sure you throw away the used pieces of Nicotine Polacrilex Gum safely. There will still be some nicotine in them -- enough to make children or small animals sick.

And -- some foods and drinks can make Nicotine Polacrilex Gum less effective, so you shouldn't eat or drink for 15 minutes before using a piece. And you shouldn't drink anything while you're chewing. If you do, the Nicotine Polacrilex Gum won't be able to do its job.

**YW:** Gee, all I have to do is use Nicotine Polacrilex Gum the right way and I can kick my smoking habit?

**YM:** There's got to be more to it than that.

**LEADER:** There is. Even though Nicotine Polacrilex Gum helps with the physical part of your addiction to cigarettes, it can't deal with the mental part. For many people, mental addiction is the hardest part to fight.

But don't panic. Lots of people make a few tries before they succeed. And there are some pretty effective techniques for dealing with the mental addiction and for boosting your willpower.

That's the subject of your next support group, down the hall. In fact, it's just about to start. Good luck to you all!

(People get up and begin shuffling out of the room)

**(END OF SIDE A)**

**Nicotine Polacrilex Gum audio Tape  
Side B**

*(Music: Peaceful and soothing. Perhaps "space music" with vaguely oriental harmonies.)*

*Mr. Yamato's classroom. The students have filed in, and are strangely quiet. (Music down.)*

*Mr. Yamato has almost no accent, and speaks somewhat precisely in a soft voice that is reassuring and comforting*

**YAMATO:** Good afternoon. I notice that you are all rather quiet. That is because of the music. It is true that peaceful music brings a quiet and relaxed state of mind. (Music down and out.) One of the things you will see as you go through your program to end your smoking habit is that relaxation is important in relieving the mental stress you may feel.

But before we become too relaxed, I would like each of you to tell me your most important reason for wanting to quit. Let's begin with you, miss.

**YW:** Oh. Well, I guess I want to quit because I don't want to smell like smoke all the time. I put on this expensive perfume, but I still smell like smoke. I don't now because I haven't had a cigarette for a couple of hours while I'm in school here.

**YAMATO:** Things will smell even better to you after you have been off cigarettes for a while. Things will smell better and taste better. But that probably isn't your most important reason for quitting, sir.

**YM:** Oh no, I want to quit basically because I figure it will be a lot better for my health. Right now, when I work out or play a little basketball I get winded pretty easy.

**YAMATO:** That's the best reason of all. You have all read the many reports that tie cigarette smoking to some serious diseases and health problems. As soon as you stop smoking, your risk of getting these diseases begins to decrease.

**OW:** I'm quitting for my health too. But I also have my niece and her two children living with me, and I don't think living in a smoky house is good for them. So I guess I'm doing it for all of us.

**OM:** Yeah, well my wife is the one who started bugging me. She makes me go out on the back porch whenever I want a smoke, and that's no fun when the weather's lousy. So I'm trying to quit. Look, I know quitting will be good for me if I can stick to it. And I know it'll save me some money. Besides, I may even get a little peace and quiet!

**YAMATO:** Excellent. The reasons you all have given are very important ones. It is good to review them in your mind when you feel the need to smoke. Remind yourself of the many reasons why you decided to quit. You might even write them down and look at them every day. In fact, there's even a wallet card in your User's Guide with space for you to do just that. Whenever you need help to overcome the urge, you can take it out and read what you wrote.

**OM:** I know one problem I'm going to have. I spend a lot of time at Neary's -- uh, this bar in my neighborhood -- because my buddies hang out there. They all smoke so it's going to be tough for me not to.

**YAMATO:** Yes, indeed it will. Perhaps you will decide not to go to Neary's for a week or so. But never lose sight of this: you want to give up smoking -- you don't want to give up your lifestyle. So sooner or later you will go back to Neary's. When you do so, it must be in a frame of mind that makes it possible for you to resist the temptation that will be all around you.

**OM:** How do I do that?

**YAMATO:** Let us see if we can find an answer. At Neary's, do you have a friend who has given up smoking?

**OM:** Yeah, Maury. He used to smoke more than anybody there. But I guess he got worried about his health, so he quit. I think he joined some kind of group. He didn't show up at Neary's for a couple of weeks, but he's back to being a regular.

**YAMATO:** There is your answer. Your friend Maury joined a support group of people who were going through the same difficulties he was. And he avoided Neary's for a while because he knew that the temptation to smoke might be more than he could resist. But after a while he had conquered his addiction well enough to come back and meet with his friends.

**OM:** Yeah, I guess that might work.

**YAMATO:** Don't forget, the first few weeks are the hardest, so that's when you should avoid temptation if you can. After that, the mental part of your dependence on cigarettes should be coming under control, and you can resume doing some of the things you may have given up for a while. Soon, you will find yourself taking pride in your ability to be comfortable in situations where others are smoking.

**OM:** So when I do feel ready to go back to Neary's I have to go with my mind made up not to smoke -- and I have to keep reminding myself of my reasons?

**YAMATO:** Exactly. If you tell your friends you're quitting smoking, they'll probably be glad to help support you in your decision, if they think you are sincere.

**OW:** I think I'll get a lot of support just by looking at the kids. If I remind myself that I'm doing it for them it will be easier than if I were just doing it for myself.

**YAMATO:** An excellent thought.

**YW:** With me I guess it's more of a habit than anything else. Pretty often I find myself smoking and I don't even remember reaching for the cigarette and lighting it.

**YAMATO:** That happens to most smokers. If there aren't any cigarettes around, you won't be able to smoke without thinking about it. That's why most people who want to quit throw away their cigarettes, lighters and ashtrays.

**YW:** Well, actually I kind of like to smoke. I guess it gives me pleasure, even though it makes my clothes smell.

**YAMATO:** That is the greatest hurdle to overcome. Smokers get pleasure out of smoking. Not out of every cigarette -- many of them are just from habit. But that first cigarette in the morning is satisfying. And a cigarette with coffee or after a meal is pleasurable for many people. Perhaps the best way to deal with this is to find a substitute pleasure that works for you. Find something to do that is pleasant and that doesn't go well with smoking.

**YM:** I smoke when I get nervous. Is there anything I can do about that?

**YAMATO:** Yes, there are techniques you can use to help you relax. For example, breathing.

**STUDENTS:** *Huh? What? Hey, I do that all the time.*

**YAMATO:** I thought that would surprise you. I am not talking about ordinary breathing -- the kind we do without thinking about it. I am talking about deep, relaxing breathing -- breathing upon which you concentrate all your attention. Perhaps, young lady, you will assist me in demonstrating.

**YW:** But I don't know anything about that.

**YAMATO:** That doesn't matter. It's really quite simple. The first thing to do is to sit up straight, but without straining yourself.

**YW:** Like this?

**YAMATO:** Yes, but you must relax. Try letting your arms dangle loosely. Shake them a bit to relax the muscles. Make sure your leg and back muscles are relaxed too. Move your head around a little to relax your neck. How does that feel?

**YW:** Pretty good.

**YAMATO:** Fine. Now, breathe out and then take a slow breath as deeply as you can.

**YW:** *(Exhales. Inhales very deeply.)*

**YAMATO:** Now, hold that breath for a few seconds. Then let it all out slowly. Wait a second and take another deep breath.

**YW:** *(Breathes.)*

**YAMATO:** How does that feel?

**YW:** Gee. I never knew you could get such a feeling from just breathing.

**YAMATO:** It is amazing, is it not? Now, to assure that deep breathing truly relaxes you, close your eyes and picture a scene that you find very pleasurable and soothing.

**YW:** Like walking on the beach?

**YAMATO:** If that is the scene that makes you feel good, yes.

**YM:** I'll go along with that. Except I like to do my walking in the woods.

**YAMATO:** Now, let's all try it. Sit straight but relaxed. Take slow, deep breaths, and think of something that makes you feel at ease.

*(Students shift around, shake, breathe a few times.)*

**OM:** Man, I never knew I could get such a kick out of breathing.

**OW:** Me, too.

**YAMATO:** That is one of the keys to helping you resist smoking at those critical times. Find something to do that occupies your mind and your body fully. This can help you not think about smoking. Your routine may be as simple as this breathing exercise, but the important thing is to find some easy activity that's right for you.

**YM:** Boy, that's great. Anything else to help us resist temptation?

**YAMATO:** Basically, anything that helps you relax. As I said at the start of the class, soothing and peaceful music is a great aid to relaxation. If you're at home and feel the need for a smoke, try putting on some soft music. Sit in a comfortable chair, relax your muscles, breathe deeply and just let yourself float.

You are beginning a process that will not be easy. But if you use Nicotine Polacrilex Gum properly, as it is explained in the User's Guide, and if you remember these tips to help you get past the mental hurdles, you will greatly increase your chances for success.

Now, we're going to spend the rest of the period just practicing muscle relaxation, deep breathing and calm, soothing mental pictures. Make yourselves comfortable and I will put on some music to help you put all thought of smoking out of your minds. I'm sure you will enjoy it.

*(Music up. Plays to end of tape.)*