

NICOTINE TRANSDERMAL SYSTEM STEP 1- nicotine patch, extended release
Physicians Total Care, Inc.

Drug Facts

Active ingredient

Nicotine, 21 mg delivered over 24 hours

Purpose

Stop smoking aid

Uses

reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.

Warnings

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

Do not use

- if you continue to smoke, chew tobacco, use snuff, use nicotine gum, or use another nicotine patch or other nicotine containing products

Ask a doctor before use if you have

- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- an allergy to adhesive tape or have skin problems, because you are more likely to get rashes.

Ask a doctor or pharmacist before use if you are

- using a non-nicotine stop smoking drug
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted

When using this product

- do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.
- if you have vivid dreams or other sleep disturbances remove this patch at bedtime

Stop use and ask a doctor if

- skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness and rapid

heartbeat

Keep out of reach of children and pets

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Save pouch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in pouch.

Directions

- **If you are under 18 years of age, ask a doctor before use**
- before using this product, read the enclosed self-help guide for complete directions and other information
- stop smoking completely when you begin using the patch
- if you smoke **more than 10 cigarettes per day**, use the following schedule below:

Weeks 1 thru 4	Weeks 5 and 6	Weeks 7 and 8
STEP 1 use one 21 mg patch/day	STEP 2 use one 14 mg patch/day	STEP 3 use one 7 mg patch/day

- if you smoke **10 or less cigarettes per day**, start with **Step 2** for 6 weeks, then **Step 3** for 2 weeks and then stop
- apply one new patch every 24 hours on skin that is dry, clean and hairless
- remove backing from patch and immediately press onto skin. Hold for 10 seconds.
- wash hands after applying or removing patch. Save pouch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in pouch.
- the used patch should be removed and a new one applied to a different skin site at the same time each day
- if you have vivid dreams, you may remove the patch at bedtime and apply a new one in the morning
- do not wear more than one patch at a time
- do not cut patch in half or into smaller pieces
- do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
- to avoid possible burns, remove patch before undergoing any MRI (magnetic resonance imaging) procedures
- stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor.

Other information

- store at 20-25°C (68-77°F)

USER'S GUIDE

Nicotine Transdermal System

STOP SMOKING AID

PATCH

HABITROL TAKE CONTROL



Your guide to help you successfully quit smoking

USER'S GUIDE

Nicotine Transdermal System

STOP SMOKING AID PATCH

HABITROL TAKE CONTROL SUPPORT PROGRAM® (with logo)

Your guide to help you successfully quit smoking

Table of Contents

I: Thinking About Quitting

Why the HABITROL Take Control® Support Program Leads to Success	3
Working Towards Success: The Stages of Change	5
Which Way Now?	8
Why I Want to Stop Smoking	8
Health Benefits of Quitting	

II: Getting Started: Your Personal Quit Plan

Setting Your Quit Date	10
Understanding Nicotine Addiction	10
Smoking and Your Body	10
Smoking and Your Mind	11
Knowing Your Triggers	12
Taming Your Triggers	12
Reducing the Urge to Smoke	12

Building Your Supporting Cast	14
Countdown to Quit Day: 10 Steps to Success	15
Rewarding Yourself	16
If You Slip	16
III: The Patch	
Important Information About this Nicotine Transdermal System	18
How the Patch Works	19
How to Use the Patch	20
IV: Weight Control Guide	
27	
V: You Are on Your Way	
29	
VI: Your Daily Success Calendar	
30	
VII: HABITROL Take Control® Support Program Resources	
34	

I: Thinking About Quitting

Nicotine Transdermal System Patch Stop Smoking Aid

Why the HABITROL Take Control® Support Program Leads to Success.

Congratulations! You've joined millions of others who have made the important and rewarding decision to quit smoking. A large percentage of smokers have already successfully quit. You can too. You've already taken the first smart step by choosing the patch and the HABITROL Take Control® Support Program. The program includes the use of nicotine replacement therapy and behavioral support, a combination that can significantly increase your chances of quitting.

The patch helps smokers quit smoking by reducing nicotine withdrawal symptoms. Many patch users will be able to stop smoking for at least a few days, but many will start smoking again. Most smokers usually have to try to quit several times before they completely stop.

Your own chances to stop smoking depend on how strongly you are addicted to nicotine, how much you want to quit, and how closely you follow a quitting program like the one that comes with this product. If you find you cannot stop or if you start smoking again after using this product, please talk to a health care professional who can help you find a program that may work better for you. First, there is the 3-step nicotine patch that delivers controlled amounts of nicotine to help reduce your withdrawal cravings for nicotine. The patch utilizes nicotine replacement therapy, and through the use of step-down dosing, gradually reduces the amount of nicotine in your system.

Second, the HABITROL Take Control® Support Program, developed by behavioral change and smoking cessation experts, recognizes that quitting smoking is a personal journey that occurs

in six stages, known as the “Stages of Change.”

The HABITROL Take Control® Support Program offers the following support elements to help you quit:

1. This **guide** will teach you how to move through the quit process by helping you to identify your reasons for quitting, manage urges to smoke, recover from slips and control your weight.

2. An optional **compact disc*** gives you more information about the patch and the six “Stages of Change.” It provides guidance about what to do at each stage to increase your chances of quitting for good, as well as, relaxation techniques to help you become and remain smoke-free. It also includes a full track of soothing instrumental music.

3. 1-888-HABITROL — our toll-free telephone support center, staffed by smoking cessation professionals, will offer you friendly support and information. Call Monday through Friday between 9 a.m. and 8 p.m. ET. You can use this resource to help you get ready to quit, manage urges, cope with withdrawal symptoms, recover from slips and deal with smoking spouses and friends.

**If you need a cassette tape instead of the compact disc, please call 1-888-HABITROL.*

Working Towards Success — The Stages of Change

Quitting smoking is a process that begins long before your quit day. Researchers have determined that smokers go through the following six “Stages of Change” while on the road to becoming smoke-free.

Pre-Contemplation Stage:

If you are in this stage, you don’t have any intention to quit smoking in the near future (i.e., within the next 6 months). You feel that the benefits you receive from smoking outweigh the costs and risks of smoking. This is called the *Pre-Contemplation Stage*. If you are in this stage right now, you are not ready to use the patch.



Contemplation Stage:

After a period of time, often years, you may begin to realize that you are “hooked,” and that smoking is affecting your health and the health of those around you. You begin to think about the benefits of quitting, but you know that quitting will be difficult. You are seriously considering quitting smoking sometime within the next six months, but you are ambivalent. This is called the *Contemplation Stage*. In this stage, you may read articles on ways to quit or on the health effects of smoking, while you would have ignored this information in the *Pre-Contemplation Stage*. You begin to imagine your life without cigarettes. You also begin to experiment with making changes. For example, you may be trying to delay your first cigarette of the day, smoke only half of some cigarettes, or not smoke in your house or car. If you are in this stage right now, you are still not ready to use the patch.

Preparation Stage:

When you’ve made the decision to quit within the next month, and you have experimented with making changes, you’ve entered the *Preparation Stage*. Most people who have purchased the patch for the first time are in this stage. Preparation is a good name for this stage because *thorough preparation greatly improves your chances of success*. Just “winging it” or relying on willpower alone is not enough. *You need a game plan that includes setting a quit date and committing to at least one person that you will make this change*. Using this guide, as well as talking to the professionals at 1-888-HABITROL, will help you become fully prepared for your quit day and beyond.

Action Stage:

On the day that you quit smoking, you are in the *Action Stage*. It’s time to set your plan in motion. You will probably experience cravings for nicotine and urges to have a cigarette throughout the day, but through preparation, you have developed multiple strategies for dealing with your “triggers,” withdrawal symptoms and those cravings or urges to smoke. It’s important to start using the patch on the morning of your quit-day to help reduce urges to

smoke and other withdrawal symptoms, such as irritability and difficulty concentrating.

Maintenance and Termination Stages:

If you are able to remain smoke-free for 6 months, you enter the *Maintenance Stage*. You like your new life, but still have occasional urges. Watch out for overconfidence. Thinking you can smoke “just one cigarette” should be a blinking neon warning sign. For most people, that one cigarette leads to two, then three, then full-time smoking again. Constantly remind yourself of the benefits you now enjoy as a nonsmoker. Have a plan ready to help you manage unexpected situations that may cause you stress and challenge your resolve to remain smoke-free. Most successful quitters will have occasional urges for many years.

Only about 1 in 5 quitters reach the *Termination Stage*, in which they have absolutely no temptation to smoke, and are 100% confident that they will never smoke again.

Your own chances to stop smoking depend on how strongly you are addicted to nicotine, how much you want to quit, and how closely you follow a quitting program like the one that comes with this product. If you find you cannot stop or if you start smoking again after using this product, please talk to a health care professional who can help you find a program that may work better for you.

the next 6 months). You feel that the benefits you receive from smoking outweigh the costs and risks of smoking. This is called the *Pre-Contemplation Stage*. If you are in this stage right now, you are not ready to use the patch.

the next 6 months). You feel that the benefits you receive from smoking outweigh the costs and risks of smoking. This is called the *Pre-Contemplation Stage*. If you are in this stage right now, you are not ready to use the patch.

Why I Want to Stop Smoking

Knowing that there are benefits to quitting is essential to your success. Writing down the reasons you want to quit on a card and keeping it with you to review can help you resist a temptation to smoke. Check off the reasons below that apply to you.

- I want control back — I’m almost always thinking about or smoking a cigarette. I feel like the cigarette is controlling me.
- I want to improve my chances of living a longer, healthier life.
- I want to spend my cigarette money on other things — maybe a vacation.
- I want more time for myself. Instead of taking those smoke breaks outside, I could be doing so many other things.
- I want to look and smell better by getting rid of that lingering odor of smoke.
- I want to set a healthier example for my children and grandchildren.

Write other reasons you have for quitting in the space below:

After completing this list, refer to it every day to reinforce your commitment to becoming a nonsmoker.

Health Benefits of Quitting

Most of us recognize the risks of smoking, such as cancer, heart disease and emphysema, but may not be aware of the many immediate and long-term benefits of quitting.

Immediate benefits in the first days and months may include:

- Breathing may get easier
- Food tastes better
- Sense of smell improves
- Walking and exercise may become easier

Remember, it's never too late to quit. Whether you're 34 or 84, your body can cleanse and start to repair the damage done by years of smoking.

II: Getting Started: Your Personal Quit Plan

Setting Your Quit Date

Now that you are motivated and committed, the next step is to choose a quit date within the next 2–3 weeks to stop smoking. Decide whether it will be easier to quit on a workday when your smoking may already be restricted, or on the weekend when you are more relaxed. You may want to consider quitting at the beginning of the week, on a Sunday or Monday. It's best to choose a date when:

- Your stress level is low
- You'll be confronted with a minimum of smoking triggers
- You will not be in a social situation with other smokers, especially those that include alcohol

Enter your quit date on Day 1 of your Daily Success Calendar, located in the back of this guide.

Understanding Nicotine Addiction

Dependence on cigarettes is a twofold problem: the physical side of addiction to nicotine and the psychological side. Preparing to deal with both in advance will help make quitting easier and more comfortable.

Smoking and your body

As you know, smoking cigarettes is addictive. Nicotine, the addictive agent, reaches your brain in just seconds after each puff. Your brain and body get used to functioning with a certain level of nicotine. Within a few hours of your last cigarette, your nicotine level drops dramatically, resulting in withdrawal symptoms for most smokers.

Common withdrawal symptoms include intense cravings for nicotine, irritability, anxiety, depression, restlessness, difficulty

concentrating, difficulty sleeping and increased appetite. Physical withdrawal symptoms usually peak within 24 to 72 hours after quitting, then decline over the next several weeks. Some smokers, however, may experience withdrawal symptoms for several months.

Staying on this patch for the full eight weeks can reduce the withdrawal symptoms you experience.

Smoking and your mind

The physical need for nicotine isn't the only reason you may find it difficult to quit smoking. You can also be psychologically dependent.

Over time you've created strong associations or "triggers" to light up a cigarette. Sometimes you smoke for comfort: "Smoking helps me relax," or "I don't feel as angry when I smoke." Sometimes it seems to make a social situation more enjoyable: "I like to smoke when I'm out having coffee with a friend or when drinking at a party." At other times, you smoke out of habit: "I light up as soon as I get in the car," "I smoke when I'm taking a break at work" or "Because I am so used to smoking, I feel uncomfortable without a cigarette in my hand."



Knowing your "triggers"

Listed to the right are some of the common situations or activities that "trigger" smoking in many people and some suggestions on how to change your habits in order to reduce your urge to smoke.

Taming Your Triggers

Here are some other common "triggers." Check off the ones that apply to you and write down how you will cope in the spaces below. Also, record other personal "triggers" and the things you plan to do instead.

Reducing the Urge to Smoke

Urges to smoke only last for a few seconds to a few minutes.

Believe it or not, the urge to smoke will pass whether you smoke or not. When an urge strikes, try the following:

1. The “Three-Second Breathing” Exercise. Nothing relaxes you more quickly than taking a deep breath. Inhale deeply through pursed lips. Hold your breath for 3 seconds. Then slowly exhale through your mouth.

If you smoke...Then try...
With your morning coffee...
Drinking hot chocolate, tea or orange juice
After a meal...
Leaving the table and doing something else or brushing your teeth
After a stressful situation...
Taking a walk or a 5 minute break
Before bed...
Reading or deep breathing
On the telephone...
Doodling on a notepad or talking while standing or walking
At parties...
Avoiding alcohol, and munch on healthy snacks
Watching T.V...
Watching T.V. while holding something else, like a stress ball,
or sitting in a different chair

2. Switch your focus. Deliberately switch your attention from having a cigarette onto something else, like reading or stretching.

3. Use mental imagery to transform the urge into something manageable. For example, imagine the urge to smoke is like feeling thirsty. Then imagine reaching for a glass of cool ice water. Feel the coolness in your throat. Your entire body feels relief. You are calm and the urge has disappeared.

<i>My Trigger</i> <i>(In the past, I smoked ...)</i>	<i>My Solution</i> <i>(Now, I will ...)</i>
<input type="checkbox"/> To concentrate	_____
<input type="checkbox"/> To relax	_____
<input type="checkbox"/> To give myself a lift	_____
<input type="checkbox"/> Because I was angry	_____
<input type="checkbox"/> Because I was bored	_____
<input type="checkbox"/> Because I felt stressed	_____
_____	_____
_____	_____

Remember when you first tried a cigarette? Remember how awful it tasted? Remember your initial dizziness? Nausea? The point is, it took some time for you to learn how to smoke. Now you can learn not to smoke. That takes time too. Sticking with the HABITROL program can help. Call 1-888-HABITROL. We can help you develop customized solutions to your personal triggers.

Building Your Supporting Cast

Quitting isn't easy. Sometimes you can feel all alone. This is where friends and family, both smokers and nonsmokers, can help. Take your friends and family through your quit plan. Once they understand why you are changing some of your old habits, they'll be in a better position to understand and support you. Tell your smoking friends of your desire to quit (truth is, many of them may have that same desire). You might be pleasantly surprised how supportive they can be. If your smoking friends express an interest in quitting, give them our number, 1-888-HABITROL, and we'll help get them started. You might even choose to quit at the same time so that you can work as a team supporting one another.

It's hard for people who have never smoked to understand what you're going through, both emotionally and physically. Be patient with them. Explain that you might be a little (or very) irritable for a while.



Countdown to Quit Day — 10 Steps to Success

1. Tape a list of your reasons for quitting on the mirror. Go over

them daily.

2. Tell one or two friends and your family. Ask for the specific help that you think you will need from each of them.
3. Use the HABITROL Take Control® Support Program.
4. Know your “triggers” and practice your coping strategies.
5. Change your routines (for example, sit in a different chair, not your smoking chair).
6. Plan how you will spend all the money you save from not smoking.
7. Freshen your environment. On the day before your quit date, clean your clothes, car and any rooms where you spend a lot of time.
8. Throw away any remaining cigarettes, ashtrays and lighters the night before your quit day.
9. Have plenty of low-calorie snacks available.
10. Use the patch as directed.

You should not smoke or use any other product containing nicotine while wearing the patch, since doing so will temporarily increase the level of nicotine in your blood. Furthermore, smoking even one cigarette reduces your chances of becoming smoke free.

Rewarding Yourself

Many people get this far and forget to reward themselves. We know that we are more likely to keep going if we get rewarded. So, in the space below, write ways that you can reward yourself at least once a day.

If You Slip

Imagine that you go out with friends and end up having a cigarette. In other words, you “slipped.” This is not a relapse back to smoking. Don’t let this mistake make you feel like a failure or like giving up. Get back on track immediately. Don’t smoke another cigarette. Figure out why you had the slip and how, in the future, you will deal with the people, places or feelings that led to smoking. Do whatever works for you. The point is that slips, like mistakes, can be great learning experiences. If you slip and need help, give us a call at 1-888-HABITROL. We’ll be happy to help you find ways to cope — without a cigarette.

If you resume smoking

If you do return to your regular smoking habit, take some time to examine what went wrong. Did you quit without being prepared? Did you have and use the support of friends and family? If you are ready to try again, we can help you evaluate and revise your

personal quit plan: call us at 1-888-HABITROL.

The patch helps smokers quit smoking by reducing nicotine withdrawal symptoms. Many patch users will be able to stop smoking for at least a few days, but many will start smoking again. Most smokers usually have to try to quit several times before they completely stop.

Your own chances to stop smoking depend on how strongly you are addicted to nicotine, how much you want to quit, and how closely you follow a quitting program like the one that comes with this product. If you find you cannot stop or if you start smoking again after using this product, please talk to a health care professional who can help you find a program that may work better for you.

And, if for some reason you are not ready to try again right now, keep these materials until you are ready. Before you set your quit date, call us to help you prepare for a successful quit.

A quick tip -- If you bought a pack of cigarettes to “just have one,” run the rest under cold water and then throw them out! Every single one! Don’t allow yourself to think that you can keep cigarettes stashed away and still resist them. Remember, the only reason to keep cigarettes around is to smoke them!

III: The Patch

Important Information About this Nicotine Transdermal System

This product is only for those who want to stop smoking. The patch helps smokers quit by reducing nicotine withdrawal symptoms. Almost half of those who use this product will be able to stop smoking for at least a few days, but many will start smoking again. Most smokers will require several attempts before they stop smoking completely. Your own chances of quitting depend on how strongly you are addicted to nicotine, how motivated you are to quit, and how closely you follow a quit program, such as this one. If you find that you cannot stop smoking, or if you start smoking again after using the patch, talk with your doctor, who can help you find a program that may work better for you.

Do not use the patch if you continue to smoke, chew tobacco or use snuff, nicotine gum, nicotine nasal spray, nicotine inhaler or any other nicotine-containing product.

Ask your doctor before use if you:

- Have heart disease or an irregular heartbeat, or if you had a recent heart attack. Nicotine can increase your heart rate.
- Have high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- Are allergic to any adhesives or patch ingredients or have skin problems, because you are more likely to get rashes.
- Are using a non-nicotine stop smoking drug.
- Take prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Keep out of reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

How the Patch Works

The patch is a nicotine transdermal system skin patch containing nicotine, the addictive agent in tobacco products. When you wear a patch, it gradually releases nicotine into your bloodstream through the skin. By replacing some of the nicotine to which your body has become accustomed from smoking, the patch helps reduce the nicotine withdrawal symptoms many people normally feel when they stop smoking. By offering three patches with different nicotine dose levels, this patch uses a step-down dosing system that allows you to gradually reduce your nicotine level by changing the patch you wear (moving to a lower dose) over an eight-week period. Nicotine replacement therapy can reduce nicotine withdrawal symptoms such as irritability, anxiety, restlessness, headaches, difficulty sleeping and concentrating, increased appetite, and craving for nicotine. By helping to reduce your physical nicotine withdrawal symptoms, the patch helps you to concentrate on the psychological aspects of quitting and to change your habits that “trigger” your nicotine cravings.

This patch program takes 8 weeks to complete, at the end of which you should stop using the patch. It is important that you keep using the patch until you have completed the entire program, and continue to use the HABITROL Take Control® Support Program when you need it.

It is important that you are firmly committed to giving up smoking.

Warnings:

- Have heart disease or an irregular heartbeat, or if you had a recent heart attack. Nicotine can increase your heart rate.
- Have high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- Are allergic to any adhesives or patch ingredients or have skin problems, because you are more likely to get rashes.
- Are using a non-nicotine stop smoking drug.
- Take prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Keep out of reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

How the Patch Works

The patch is a nicotine transdermal system skin patch containing nicotine, the addictive agent in tobacco products.

When you wear a patch, it gradually releases nicotine into your bloodstream through the skin. By replacing some of the nicotine to which your body has become accustomed from smoking, the patch helps reduce the nicotine withdrawal symptoms many people normally feel when they stop smoking. By offering three patches with different nicotine dose levels, this patch uses a step-down dosing system that allows you to gradually reduce your nicotine level by changing the patch you wear (moving to a lower dose) over an eight-week period. Nicotine replacement therapy can reduce nicotine withdrawal symptoms such as irritability, anxiety, restlessness, headaches, difficulty sleeping and concentrating, increased appetite, and craving for nicotine. By helping to reduce your physical nicotine withdrawal symptoms, the patch helps you to concentrate on the psychological aspects of quitting and to change your habits that “trigger” your nicotine cravings. This patch program takes 8 weeks to complete, at the end of which you should stop using the patch. It is important that you keep using the patch until you have completed the entire program, and continue to use the HABITROL Take Control® Support Program when you need it.

Why wearing a nicotine patch isn't as bad as smoking?

By placing a nicotine patch on your skin, you are NOT inhaling the harmful tars, toxins and chemicals found in cigarettes. These are the most dangerous parts of the cigarette.

And, because you're not smoking while wearing the patch, there's no second-hand smoke or odors to affect your family and friends.

How to Use the Patch

It is important that you are firmly committed to giving up smoking.

Warnings:

• If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.

Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

• Do not use if you continue to smoke, chew tobacco, use snuff, use nicotine gum, or use another nicotine patch or other nicotine containing products.

• Ask a doctor before use if you have heart disease, have had a recent heart attack, or have an irregular heartbeat. Nicotine can increase your heart rate.

• Ask a doctor before use if you have high blood pressure not controlled with medication. Nicotine can increase your blood pressure.

• Ask a doctor before use if you have an allergy to adhesive tape or have skin problems because you are more likely to

get rashes with patch use.

- Ask a doctor or pharmacist before use if you are using a non-nicotine stop smoking drug.
- Ask a doctor or pharmacist before use if you are taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.
- When using this product, do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.
- When using this product, if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning.
- Stop use and ask a doctor if skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash.
- Stop use and ask a doctor if irregular heartbeat or palpitations occur.
- Stop use and ask a doctor if you get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness and rapid heartbeat.
- Keep unused and used patches out of the reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Save pouch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in pouch. Do not wear more than one patch at a time.
- Do not cut the patch in half or into smaller pieces.
- Do not leave the patch on for more than 24 hours because it may irritate your skin and it loses strength after 24 hours.
- To avoid possible burns, remove patch before undergoing any MRI (Magnetic Resonance Imaging) procedures.
- Stop using the patch at the end of 8 weeks. The patch has been tested in 3 month studies and long

See chart on following page.

First, it is important that you are well prepared to give up smoking. If you are under 18 years of age, ask a doctor before use.

If you smoke more than 10 cigarettes per day: Begin with Step 1. Use the 21mg patch for 4 weeks, then 14mg patch for 2 weeks, and 7mg patch for 2 weeks.		
Weeks 1-4	Weeks 5 and 6	Weeks 7 and 8
Step 1 21 mg/day	Step 2 14 mg/day	Step 3 7 mg/day

If you smoke 10 or less cigarettes per day: Do not begin with Step 1.

Begin with Step 2, 14mg patch for 6 weeks, and 7 mg patch for 2 weeks.

Weeks 1-6	Weeks 7 and 8
Step 2 14 mg/day	Step 3 7 mg/day

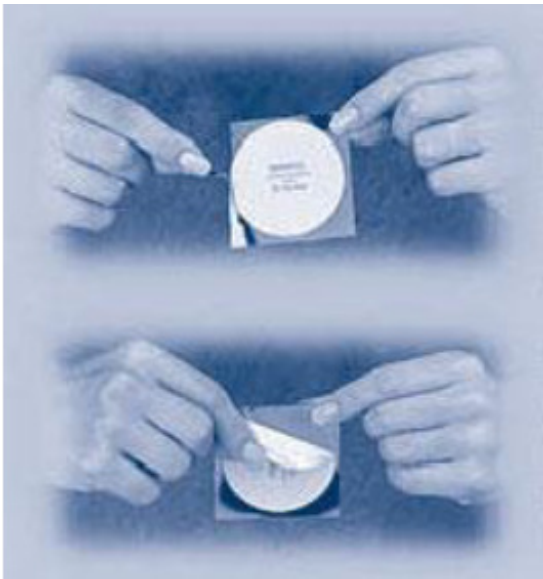
If you smoke 10 or less cigarettes per day:

- Do not use Step 1 Patch (21 mg/ day). Begin with Step 2 Patch (14mg/day) for 6 weeks, use Step 3 Patch (7mg/day) for 2 weeks and then stop.
- Steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chance of quitting successfully.
- Stop at the end of eight weeks.

Lowering your patch dosage over 8 weeks will help you overcome your physical cravings for nicotine. You should talk to your doctor if, after you complete 8 weeks of patch use, you feel you need to continue therapy.

How to apply the Nicotine Transdermal System Patch

1. Choose a clean, dry, non hairy area of skin on your upper body or the outer part of your arm. Do not put a patch on skin that is very oily, burned, broken out, cut or irritated in any way. Immediately before applying the patch, wash your hands and the skin area with plain soap and water and dry completely. Avoid using any soap, lotion, hand cream, tanning lotion or oil, bath oil or insect repellent that contains aloe, lanolin or glycerin as a moisturizer. These products can leave a moisturizing film on your skin, which can interfere with the adherence of the patch.
2. Do not remove the patch from its sealed, protective pouch until you are ready to use it. Carefully cut open the child-resistant pouch along the dotted line, as indicated. If the new patch is cut, throw it away. Save pouch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in pouch.

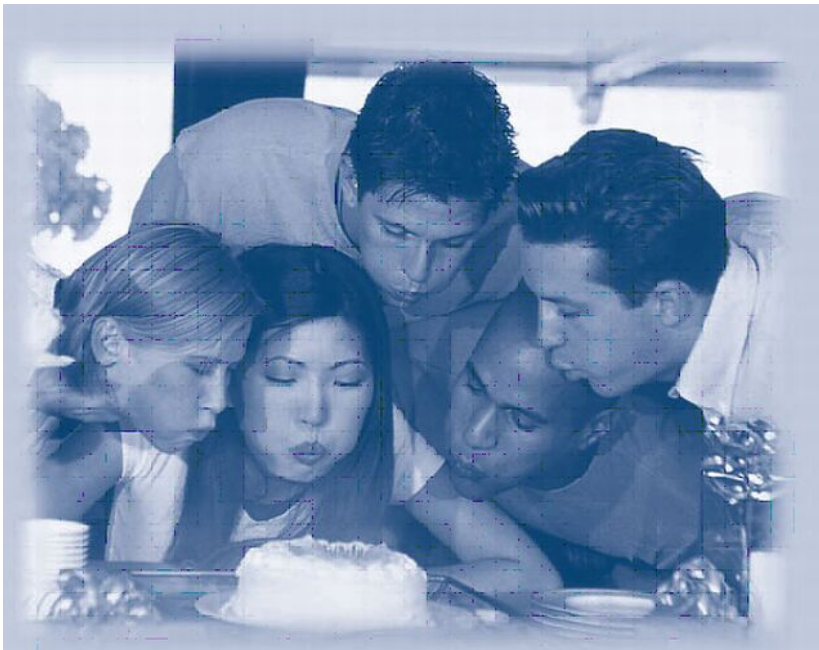


3. A shiny protective liner covers the sticky side of the patch where it contacts the skin. The liner has a precut slit to help you remove it from the patch. With the silver side facing you, pull the liner away from the patch, starting at the precut slit. Hold the patch at the edge (touch the sticky side as little as possible) and pull off the other piece of the protective liner. Throw this liner away.

4. Immediately apply the sticky side of the patch to your skin. Press the patch firmly against your skin with the palm of your hand for about 10 seconds. Make sure it sticks well to your skin, especially around the edges.

5. When you have finished applying or removing the patch, wash your hands with water only. Nicotine on your hands could get into your eyes and nose and could cause stinging, redness or irritation.

6. After 24 hours, remove the patch you have been wearing. *If you remove and apply the patch at about the same time each day, it will help you to remember when to put on a new patch.* Choose a different place on your skin to apply the next patch and repeat steps 1 through 5. Do not reapply a patch to a previously used skin site for at least 1 week. Do not leave the patch on for more than 24 hours, because it may irritate your skin and loses strength after 24 hours. Do not wear more than one patch at the same time, and do not cut a patch in half or into smaller pieces to wear.



If you have trouble sleeping

You should wear the patch 24 hours a day. This may help overcome your morning cravings for nicotine. However, if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new patch the following morning. The patch should be applied at approximately the same time each day.

If your patch comes off

If your patch falls off, put on a new one. Then remove this new patch at your regular time to keep your schedule the same. When applying the patch, be sure to press it firmly onto your skin with the palm of your hand for about 10 seconds, making sure that the patch sticks well, especially around the edges.

If your patch gets wet

Water will not harm or affect the patch you are wearing. You can take a bath or a shower, or you can swim while you are wearing the patch.

Disposing of the patch

Save pouch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in pouch. Keep all used patches out of reach of children and pets.

Storage instructions

Keep the patch in its protective pouch until you are ready to use it. Store your patches between 20-25°C (68-77°F), because the patch is sensitive to heat. The inside of your car, for example, can reach much higher temperatures in the summer. Keep all unused patches out of the reach of children and pets.

If your skin reacts to the patch

When you first put on a patch, mild itching, burning, or tingling at the patch application site is normal and should go away within an hour. After you remove a patch, the skin under the patch might be somewhat red. Your skin should not stay red for more than a day. If you have a skin rash or redness caused by the patch that does not go away after 4 days, or your skin swells, call your doctor. Do not put on a new patch; you may be allergic to one of the components of the patch.

Other side effects you may experience

While wearing a nicotine replacement patch, you may experience one or more of the following side effects: nausea, dizziness, dry mouth, diarrhea, nervousness or restlessness, headache, vivid dreams or other sleep disturbances, and irritability.

If you experience any of the following side effects, immediately remove the patch and call your doctor:

- Severe skin irritation or discoloration
- Irregular heartbeats or palpitations
- Severe chest pain or tightening
- Symptoms of nicotine overdose, such as pallor (extreme paleness), cold sweat, nausea, abnormal salivation, vomiting, abdominal pain or severe headache, disturbed hearing or vision, dizziness, mental confusion or weakness.

IV: Weight Control Guide

Why You May Gain Weight After You Quit Smoking

It's perfectly normal to gain some weight when you stop smoking. But don't panic. Sometimes the weight change is simply a result of a change in your body's metabolism. This is caused by your body's withdrawal from nicotine. Your metabolism is simply returning to that of a nonsmoker. Besides, the average weight gain is only about five to ten pounds, and as you will see, there are things you can do to help control it.

Another source of extra pounds is the need for oral gratification. If you use food as a temporary substitute for cigarettes, you may gain weight. If you feel some concern about your weight, remember: a small weight gain is better than the high health risks associated with smoking.

The following tips will help you minimize the weight gain

while you quit smoking.

How to control your weight by watching how and what you eat

Some general tips:

- Replace fattening snack foods with healthy, low-calorie snacks
- Keep low-fat, low-calorie snacks in the car
- Broil, boil, poach, or steam food instead of frying
- Remove fat from meat and skin from poultry
- Eat slowly and you'll feel full sooner on less food
- Try eating several small meals a day instead of three big ones
- Drink a large glass of water before a meal

How to control your weight through the benefits of exercise

One of the best ways to control your weight is to move more. So if you already exercise regularly, keep it up. If not, start with small increases in your daily activity.

We're NOT talking about running a marathon. We're talking about walking to the corner store instead of hopping in the car. Or, walking up three flights of stairs instead of taking the elevator. Maybe you should rediscover your bicycle, take up golf or go for a swim.

A little exercise will do more than you think:

- It reduces possible weight gain while quitting smoking
- It can improve your sleeping
- It can make you feel better in general
- It reduces possible weight gain while quitting smoking



V: You are on Your Way!

HABITROL Take Control® Support Program.

Your Daily Success Calendar

(for those who smoke more than 10 cigarettes per day.*)

Congratulations again on your decision to quit smoking. By incorporating the behavior-changing tools discussed in this guide into your everyday life, you are on your way to successfully becoming and remaining smoke-free. Continue to reinforce your commitment to remain smoke-free by reading this guide again, listening to the CD, or calling 1-888-HABITROL. While you are taking control with the Habitrol Take Control® Support Program, don't forget to celebrate your successes along the way.



**CHECK OFF EACH DAY AS A NONSMOKER AND
WATCH THOSE SUCCESSFUL DAYS ACCUMULATE**

WEEK 1: QUIT <i>The date is:</i> It's your first day as a non-smoker! Congratulations! Start off the day with your first Step 1 (21 mg) patch instead of a cigarette!	DAY 2 Avoid your triggers today. Listen to the HABITROL Take Control® CD.	DAY 3 Remember to switch your focus when you think of a cigarette – think of something else, like how much healthier you'll be.	DAY 4 Are you rewarding yourself?	DAY 5 Dry clean or wash clothes to get rid of the cigarette smell.	DAY 6 Try the Three-Second Breathing Exercise.	DAY 7 It's a good idea to review "Taming Your Triggers" (page 12).
WEEK 2 DAY 8 You made it through the crucial first week!	DAY 9 Don't forget to change your patch every day.	DAY 10 What triggers did you tame today?	DAY 11 Have you listened to the HABITROL Take Control® CD lately?	DAY 12 Did you remember to pick up more patches?	DAY 13 Make sure you have healthy snacks on hand.	DAY 14 Way to go! Two whole weeks without smoking!
WEEK 3 DAY 15 Treat yourself today! Go to the movies or the park	DAY 16 Remember to switch your focus when the urge strikes.	DAY 17 List the triggers you've tamed. Are you proud of yourself?	DAY 18 Check you patch supply. Do you need more patches?	DAY 19 Are you exercising enough? Exercise is a great stress reliever!	DAY 20 Think about encouraging a friend to stop smoking.	DAY 21 Celebrate! Three weeks of no smoking!
WEEK 4 DAY 22 You deserve a reward! Do something special for yourself.	DAY 23 Doesn't food taste better these days?	DAY 24 Was today trigger-free?	DAY 25 The urge to smoke will pass. Stay committed!	DAY 26 Remember to get up and move. Try a new exercise today.	DAY 27 Treat yourself to a bottle of cologne to celebrate your improved sense of smell.	DAY 28 Tomorrow, you step down to the next lower strength patch.

Toll Free:
1-888-HABITROL
 (1-888-422-4876)

You may want to note how you're feeling, too. Each day renew your commitment to being a nonsmoker.

***If you smoke 10 or less cigarettes per day, start with the Step 2, 14 mg patch for 6 weeks, then step 3, 7 mg patch for 2 weeks.**

**CHECK OFF EACH DAY AS A NONSMOKER AND
WATCH THOSE SUCCESSFUL DAYS ACCUMULATE**

WEEK 5 DAY 29 Can you believe it? Four whole weeks! Step down to the 14 mg/day patch, which is Step 2.	DAY 30 Take one day at a time.	DAY 31 Admit it, you're feeling great!	DAY 32 Don't forget to call a friend if you need some extra TLC.	DAY 33 Ever think about how much money you'll save being a nonsmoker!	DAY 34 Keep exercising.	DAY 35 List any surprise triggers and how you tamed them.
WEEK 6 DAY 36 Expecting a high-pressure day? Prepare yourself by reviewing "Taming Your Triggers" (page 12).	DAY 37 Try something new. Take up a hobby.	DAY 38 Don't forget to switch your focus!	DAY 39 Have you rewarded yourself lately?	DAY 40 See how many successful smoke-free days you've had!	DAY 41 Take a walk and renew your commitment.	DAY 42 Is it time to buy more patches?
WEEK 7 DAY 43 A big congratulations! You're coming down the home stretch. Step down to the 7mg/day patch, which is Step 3.	DAY 44 Your confidence about dealing with triggers has grown.	DAY 45 Review your reasons for quitting.	DAY 46 Remember to keep a healthy snack on hand.	DAY 47 Need some added support? Call a friend or 1(888) HABITROL.	DAY 48 Daily exercise is still your best defense.	DAY 49 Stronger than you thought you were. Congratulations!
WEEK 8 DAY 50 Your last week on the patch!	DAY 51 You're a hero!	DAY 52 Think of a way to celebrate.	DAY 53 Listen to your CD again.	DAY 54 Are you feeling a great sense of freedom?	DAY 55 Buy yourself a gift today.	DAY 56 Don't worry about going "solo" (without the patch). You are a success!

Toll Free:
**1-888-
HABITROL**
(1-888-422-
4876)

The HABITROL Take Control® Support Program

is committed to your success.

*You are invited to use the
HABITROL Take Control® Support Program!
It's FREE and only takes a few minutes to call.*

Call 1-888-HABITROL (1-888-422-4876)

Call now for this FREE program to help you successfully quit smoking!

With FREE Access To:

- **COUNSELING**
- **QUITTING TIPS**
- **PERSONALIZED SUPPORT**
- **INFORMATION ABOUT QUITTING SMOKING**

HABITROL Take Control Support Program® (with logo)

Keep this card in your wallet, for easy access anytime.

(Side 1) (CREDIT CARD FLIP-OUT/Cut along dotted line

10 Steps to Success

1. Tape a list of your reasons for quitting on the mirror. Go over them daily.
2. Tell one or two friends and your family. Ask for the specific help that you think you will need from each of them.
3. Use the HABITROL Take Control® Support Program.
4. Know your "triggers," and practice your coping strategies.
5. Change your routines (for example, sit in a different chair, not your smoking chair).
6. Plan how you will spend all the money you save from not smoking.
7. Freshen your environment. On the day before your quit date, clean your clothes, car and any rooms where you spend a lot of time.
8. Throw away any remaining cigarettes, ashtrays and lighters the night before your quit day.
9. Have plenty of low-calorie snacks available.
10. Use the patch as directed

Nicotine Transdermal System

STOP SMOKING AID PATCH

HABITROL TAKE CONTROL SUPPORT PROGRAM® (with logo)

Call 1-888-HABITROL (1-888-422-4876)

*Keep this card in your wallet,
for easy access anytime.*



Nicotine Transdermal System

STOP SMOKING AID
PATCH

HABITROL TAKE CONTROL



Call 1-888-HABITROL (1-888-422-4876)

©2000 Novartis Consumer Health, Inc.
88003P

Inactive ingredients

acrylate adhesive, aluminized polyester, cellulose paper, methacrylic acid copolymer

Comments or Questions?

Call **1-800-585-8682**

Additional information

Habitrol Take Control Support Program® (with logo)

Nicotine Transdermal System Patch

STOP SMOKING AID

STEP 1 logo™ 21 mg	STEP 2 logo™ 14 mg	STEP 3 logo® 7 mg
21 mg delivered over 24 hours	14 mg delivered over 24 hours	7 mg delivered over 24 hours
IF YOU SMOKE MORE THAN 10 CIGARETTES PER DAY: START WITH STEP 1	IF YOU SMOKE MORE THAN 10 CIGARETTES PER DAY: USE AFTER COMPLETING STEP 1	FOR USE AFTER COMPLETING STEP 2
IF YOU SMOKE 10 OR LESS CIGARETTES PER DAY: START WITH STEP 2	IF YOU SMOKE 10 OR LESS CIGARETTES PER DAY: START WITH STEP 2	

Includes: Behavior Support Program *with* self-help guide

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. Use one patch daily according to directions.
3. Complete the full treatment program.
4. Do not use patch for more than 8 weeks.
5. Use patch with a behavioral support program, such as the one described in the enclosed booklet and on the compact disc.

• Not for sale to persons 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.

Pouch Image:

Nicotine Transdermal System

PATCH

21 mg delivered over 24 hours

STOP SMOKING AID

21mg

STEP 1



DO NOT OPEN POUCH UNTIL READY TO USE.

DIRECTIONS: Apply one patch to a dry, clean, hairless portion of upper body or arms. Refer to Self-Help Guide for detailed directions.

DO NOT CUT PATCH. KEEP OUT OF REACH OF CHILDREN AND PETS.

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Save pouch to use for patch disposal. Dispose of the used patch by folding sticky ends together and putting in pouch.

Store at 20-25°C (68-77°F).

DO NOT USE IF INDIVIDUAL POUCH IS OPEN OR TORN, OR IF PATCH IS CUT.

Distributed by:

Novartis Consumer Health, Inc.

Parsippany, NJ 07054-0622 ©2006 Novartis

EXP

LOT

28016F

TO OPEN CUT ALONG DOTTED LINE



● PMS 282

● PMS 485

Principal Display



NDC 54868-5821-0

NICOTINE TRANSDERMAL SYSTEM STEP 1				
nicotine patch, extended release				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5821(NDC:0067-5126)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	21 mg in 24 h	
Inactive Ingredients				
	Ingredient Name	Strength		
	METHACRYLIC ACID (UNII: 1CS02G8656)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5821-0	7 in 1 CARTON		
1		1 in 1 POUCH		
1		24 h in 1 PATCH		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA020076	09/19/2007		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 5/2012

Physicians Total Care, Inc.