

**NICOTINE TRANSDERMAL SYSTEM- nicotine**  
**Dr. Reddys Laboratories Inc.**

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**Drug Facts**

***Active ingredient Step 1 (in each patch)***

Nicotine, 21 mg delivered over 24 hours

***Active ingredient Step 2 (in each patch)***

Nicotine, 14 mg delivered over 24 hours

***Active ingredient Step 3 (in each patch)***

Nicotine, 7 mg delivered over 24 hours

***Purpose***

Stop smoking aid

***Use***

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 blood stream 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:

STEP 1	STEP 2	STEP 3
Use one 21mg patch/day	Use one 14mg patch/day	Use one 7mg patch/day
Weeks 1-4	Weeks 5-6	Weeks 7-8

- 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)

### ***Inactive ingredients***

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

### ***Questions or comments?***

call **1-800-585-8682**

Weekdays (9am-8pm ET) or visit us at [www.habitrol.com](http://www.habitrol.com)

### **TO INCREASE YOUR SUCCESS IN QUITTING:**

1. You must be motivated to quit.
2. Use one patch daily according to directions.
3. It is important to complete treatment.
4. If you feel you need to use the patch for a longer period to keep from smoking, talk to your health care provider.
5. Use patch with a behavioural support program, such as the one described in the enclosed booklet.

For your family's protection, patches are supplied in child-resistant pouches. **Do not use if individual pouch is open or torn.**

- **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.**

### **Principal Display Panel Kit**

**Nicotine Transdermal System**PATCH Kit



TO INCREASE YOUR SUCCESS IN QUITTING:



1. You must be motivated to quit.
2. Use one patch daily according to directions.
3. It is important to complete treatment.
4. If you feel you need to use the patch for a longer period to keep from smoking, talk to your health care provider.
5. Use patch with a behavioral support program, such as the one described in the enclosed booklet.

NDC 43598-445-56



Nicotine Transdermal System PATCH KIT Contains 21 mg, 14 mg and 7 mg delivered over 24 hours STOP SMOKING AID



Nicotine Transdermal System PATCH KIT Contains 21 mg, 14 mg and 7 mg delivered over 24 hours INCLUDES ALL 3 STEPS



- STEP 1**  
21 mg delivered over 24 hours  
Contains 28 Patches (4 week supply)
- STEP 2**  
14 mg delivered over 24 hours  
Contains 14 Patches (2 week supply)
- STEP 3**  
7 mg delivered over 24 hours  
Contains 14 Patches (2 week supply)

Includes: Behavior Support Program with self-help guide

COMPLETE STOP SMOKING AID KIT - USE ONLY IF YOU SMOKE MORE THAN 10 CIGARETTES PER DAY

56 PATCHES

For your family's protection, patches are supplied in child-resistant pouches. Do not use if individual pouch is open or torn.

See self-help guide inside. See bottom panel for lot number and expiration date.

Distributed by: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540

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.

Drug Facts

Active ingredient (in each patch) Purpose Nicotine, 21 mg delivered over 24 hours Stop smoking aid Nicotine, 14 mg delivered over 24 hours Stop smoking aid Nicotine, 7 mg delivered over 24 hours Stop smoking aid

Use 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 risk to your child from this medicine are not fully known.

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. stomach ulcer or diabetes. History of seizures.

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 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 you have symptoms of an allergic reaction (such as difficulty breathing or rash)

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 taping sticky ends together and putting in pouch.

Drug Facts (continued)

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 begin using the patch on your quit day if you smoke more than 10 cigarettes per day, use the following schedule below

- |                                                  |                                                 |                                                |
|--------------------------------------------------|-------------------------------------------------|------------------------------------------------|
| Weeks 1 thru 4<br>STEP 1 use one 21 mg patch/day | Weeks 5 and 6<br>STEP 2 use one 14 mg patch/day | Weeks 7 and 8<br>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
  - 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 taping 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
  - it is important to complete treatment. If you feel you need to use the patch for a longer period to keep from smoking, talk to your health care provider.

Other information - store at 20-25°C (68-77°F)

Inactive ingredients acrylate adhesive, aluminum polyester, cellulose paper, methacrylic acid copolymers

Comments or questions? Call 1-800-545-5682 weekdays (8am-5pm ET) or visit us at www.habitrol.com



NICOTINE TRANSDERMAL SYSTEM

nicotine kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:43598-445

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-445-56	56 in 1 CARTON	05/14/2015	
1		1 in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		1
Part 2		1
Part 3		1

Part 1 of 3

NICOTINE TRANSDERMAL SYSTEM

nicotine patch, extended release

## Product Information

Route of Administration TRANSDERMAL

## 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)	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020076	05/14/2015	

## Part 2 of 3

### NICOTINE TRANSDERMAL SYSTEM

nicotine patch, extended release

## Product Information

Route of Administration TRANSDERMAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Nicotine (UNII: 6M3C89ZY6R) (Nicotine - UNII:6M3C89ZY6R)	Nicotine	14 mg in 24 h

## Inactive Ingredients

Ingredient Name	Strength
Methacrylic Acid (UNII: 1CS02G8656)	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020076	05/14/2015	

## Part 3 of 3

### NICOTINE TRANSDERMAL SYSTEM

nicotine patch, extended release

#### Product Information

**Route of Administration** TRANSDERMAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Nicotine (UNII: 6M3C89ZY6R) (Nicotine - UNII:6M3C89ZY6R)	Nicotine	7 mg in 24 h

#### Inactive Ingredients

Ingredient Name	Strength
Methacrylic Acid (UNII: 1CS02G8656)	

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020076	05/14/2015	

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020076	05/14/2015	

**Labeler** - Dr. Reddys Laboratories Inc. (802315887)

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Dr. Reddys Laboratories Inc.