

**NICOTINE TRANSDERMAL SYSTEM PATCH STEP 1- nicotine transdermal system patch patch, extended release**  
**NICOTINE TRANSDERMAL SYSTEM PATCH STEP 2- nicotine transdermal system patch patch, extended release**  
**NICOTINE TRANSDERMAL SYSTEM PATCH STEP 3- nicotine transdermal system patch patch, extended release**  
**BluePoint Laboratories**

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**Nicotine Transdermal System Patch**  
**Stop Smoking Aid**

***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 SECTION**

**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.

**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**

- 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**

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 rashirregular 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 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
- 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	Weeks 5 and 6	Weeks 7 and 8
<b>STEP 1</b> use one 21 mg patch/day	<b>STEP 2</b> use one 14 mg patch/day	<b>STEP 3</b> 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 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
- 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, aluminized polyester, cellulose paper, methacrylic acid copolymer

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

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

Weekdays (9am-8pm EST)

### **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 STEP 1

NDC 68001-699-88

## Nicotine Transdermal System Patch

21 mg delivered over 24 hours

### STOP SMOKING AID

21 mg

Includes: Behavior Support Program with self-help guide

### STEP 1

IF YOU SMOKE **MORE** THAN 10 CIGARETTES PER DAY: START WITH STEP 1

IF YOU SMOKE 10 OR **LESS** CIGARETTES PER DAY: START WITH STEP 2

**7 Patches** (1 Week Kit)

The full treatment course for Step 1 is 28 patches (4 weeks); this package contains 7 patches (1 week course) only. Read the enclosed self-help guide for additional information.

NDC 68001-699-90

## Nicotine Transdermal System Patch

21 mg delivered over 24 hours

# STOP SMOKING AID

21 mg

Includes: Behavior Support Program with self-help guide

## STEP 1

IF YOU SMOKE **MORE** THAN 10 CIGARETTES PER DAY: START WITH STEP 1

IF YOU SMOKE 10 OR **LESS** CIGARETTES PER DAY: START WITH STEP 2

14 Patches (2 Week Kit)

The full treatment course for Step 1 is 28 patches (4 weeks); this package contains 14 patches (2 week course) only. Read the enclosed self-help guide for additional information.



NDC 68001-699-91

## Nicotine Transdermal System Patch

21 mg delivered over 24 hours

## STOP SMOKING AID

21 mg

Includes: Behavior Support Program with self-help guide

## STEP 1

IF YOU SMOKE **MORE** THAN 10 CIGARETTES PER DAY: START WITH STEP 1

IF YOU SMOKE 10 OR **LESS** CIGARETTES PER DAY: START WITH STEP 2

## 28 Patches (4 Week Kit)

The full treatment course for Step 1 is 28 patches (4 weeks).

**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.

**STEP 1**

NDC 68001-699-91

compare to Habitrol® active ingredient\*

**STEP 1 Nicotine Transdermal System Patch**

21 mg delivered over 24 hours

**STOP SMOKING AID**

**21 mg**

Includes: Behavior Support Program with self-help guide

IF YOU SMOKE MORE THAN 10 CIGARETTES PER DAY: START WITH STEP 1

IF YOU SMOKE 10 OR LESS CIGARETTES PER DAY: START WITH STEP 2

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.

**BluePoint LABORATORIES**

**28 Patches (4 Week Kit)**

\*Habitrol® is a registered trademark of Dr. Reddy's Laboratories SA.

Manufactured for: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540 For BluePoint Laboratories REV: 12/25

**Drug Facts**

**Active ingredient (in each patch)** Nicotine, 21 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.

**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**

- 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**

- 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 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
- 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	Weeks 5 and 6	Weeks 7 and 8
<b>STEP 1</b> use one 21 mg patch/day	<b>STEP 2</b> use one 14 mg patch/day	<b>STEP 3</b> 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 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) procedure
- 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, aluminumized polyester, cellulose paper, methacrylic acid copolymer

**Comments or Questions?** Call 1-800-585-9682 Weekdays (9am-5pm EST)

See bottom panel for lot number and expiration date.

**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 STEP 2

NDC 68001-698-88

## Nicotine Transdermal System Patch

14 mg delivered over 24 hours

**STOP SMOKING AID**

**14 mg**

Includes: Behavior Support Program with self-help guide

## STEP 2

IF YOU SMOKE **MORE** THAN 10 CIGARETTES PER DAY: USE AFTER COMPLETING STEP 1

IF YOU SMOKE 10 OR **LESS** CIGARETTES PER DAY: START WITH STEP 2

## 7 Patches (1 Week Kit)



NDC 68001-698-90

## Nicotine Transdermal System Patch

14 mg delivered over 24 hours

**STOP SMOKING AID**

**14 mg**

Includes: Behavior Support Program with self-help guide

**STEP 2**

IF YOU SMOKE **MORE** THAN 10 CIGARETTES PER DAY: USE AFTER COMPLETING STEP 1

IF YOU SMOKE 10 OR **LESS** CIGARETTES PER DAY: START WITH STEP 2

**14 Patches** (2 Week Kit)



**Principal Display Panel STEP 3**  
 NDC 68001-697-88  
**Nicotine Transdermal System Patch**  
 7 mg delivered over 24 hours  
**STOP SMOKING AID**  
**7 mg**  
 Includes: Behavior Support Program with self-help guide  
**STEP 3**  
 FOR USE AFTER COMPLETING STEP 2  
**7 Patches (1 Week 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.

**STEP 2**  
**Nicotine Transdermal System Patch**  
 14 mg delivered over 24 hours  
**STOP SMOKING AID**

NDC 68001-698-90

compare to Habitrol® active ingredient\*

**STEP 2**  
**Nicotine Transdermal System Patch**  
 14 mg delivered over 24 hours  
**STOP SMOKING AID**

**14 mg**

Includes: Behavior Support Program with self-help guide

IF YOU SMOKE MORE THAN 10 CIGARETTES PER DAY:  
 USE AFTER COMPLETING STEP 1

IF YOU SMOKE 10 OR LESS CIGARETTES PER DAY: START WITH STEP 2

**BluePoint LABORATORIES**

**14 Patches (2 Week Kit)**

\*Habitrol® is a registered trademark of Dr. Reddy's Laboratories SA.  
 Manufactured for: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540 For BluePoint Laboratories  
 REV: 12/25

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NDC 68001-697-90

## Nicotine Transdermal System Patch

7 mg delivered over 24 hours

**STOP SMOKING AID**

**7 mg**

Includes: Behavior Support Program with self-help guide

**STEP 3**

FOR USE AFTER COMPLETING STEP 2

**14 Patches (2 Week Kit)**

PPA0GL0SL

1 3 2 1 5 0 9 8 2

**STEP 3**

**7 mg**

**STOP SMOKING AID**

**TO INCREASE YOUR SUCCESS IN QUITTING:**

- You must be motivated to quit.
- Use one patch daily according to directions.
- 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.
- Use patch with a behavioral support program, such as the one described in the enclosed booklet.

**STEP 3 Nicotine Transdermal System Patch**

7 mg delivered over 24 hours

**STOP SMOKING AID**

NDC 68001-697-90

compare to Habitrol® active ingredient\*

**STEP 3 Nicotine Transdermal System Patch**

7 mg delivered over 24 hours

**STOP SMOKING AID**

**STEP 3 Nicotine Transdermal System Patch**

7 mg delivered over 24 hours

**STOP SMOKING AID**

Includes: Behavior Support Program with self-help guide

FOR USE AFTER COMPLETING STEP 2

14 Patches (2 Week Kit)

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.

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\*Habitrol® is a registered trademark of Dr. Reddy's Laboratories SA.

Manufactured for: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540 For BluePoint Laboratories

REV: 12/25

**Drug Facts**

**Active ingredient (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.

**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:**

- 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:**

- If you have vivid dreams or other sleep disturbances remove this patch at bedtime.
- If you use alcohol, avoid alcohol. Nicotine may increase the effects of alcohol.
- If you get a rash, stop using this product. If you have a rash, stop using this product.
- If you get a rash, stop using this product. If you have a rash, stop using this product.

**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 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.
- begin using the patch on your quit day.
- If you smoke more than 10 cigarettes per day, use the following schedule below:

<b>Weeks 1 thru 4</b>	<b>Weeks 5 and 6</b>	<b>Weeks 7 and 8</b>
<b>STEP 1</b> use one 21 mg patch/day	<b>STEP 2</b> use one 14 mg patch/day	<b>STEP 3</b> 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 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.
- 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 copolymer

**Comments or Questions?** Call 1-800-545-8822 weekdays (8am-10pm EST)

See bottom panel for lot number and expiration date.

• 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.

## NICOTINE TRANSDERMAL SYSTEM PATCH STEP 1

nicotine transdermal system patch, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68001-699
<b>Route of Administration</b>	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)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-699-90	14 in 1 CARTON	05/11/2026	

1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:68001-699-88	7 in 1 CARTON	05/11/2026	
2		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:68001-699-91	28 in 1 CARTON	05/11/2026	
3		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020076	05/11/2026	

## NICOTINE TRANSDERMAL SYSTEM PATCH STEP 2

nicotine transdermal system patch patch, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68001-698
<b>Route of Administration</b>	TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	14 mg in 24 h

### Inactive Ingredients

Ingredient Name	Strength
<b>METHACRYLIC ACID</b> (UNII: 1CS02G8656)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-698-90	14 in 1 CARTON	05/11/2026	
1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:68001-698-88	7 in 1 CARTON	05/11/2026	
2		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020076	05/11/2026	

## NICOTINE TRANSDERMAL SYSTEM PATCH STEP 3

nicotine transdermal system patch patch, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-697
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)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-697-90	14 in 1 CARTON	05/11/2026	
1		24 h in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:68001-697-88	7 in 1 CARTON	05/11/2026	
2		24 h in 1 PATCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020076	05/11/2026	

**Labeler** - BluePoint Laboratories (985523874)

**Registrant** - Dr. Reddy's Laboratories Inc. (802315887)

