

HABITROL STEP 1- nicotine transdermal system patch patch, extended release

HABITROL STEP 2- nicotine transdermal system patch patch, extended release

HABITROL STEP 3- nicotine transdermal system patch patch, extended release

Dr. Reddy's Laboratories Inc.

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 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
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
- 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 ET) or visit us at 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 STEP 1

NDC 55741-448-74

**Habitrol®
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.



Principal Display Panel STEP 2

NDC 55741-447-74

Habitrol® 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)



Drug Facts

Active ingredient (in each patch) Nicotine, 14 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 or 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
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
 • 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, aminized polyester, cellulose paper, methacrylic acid copolymer

Comments or Questions? call 1-800-895-8882 Weekdays (8am-10pm ET) or visit us at www.habitrol.com

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.



STEP 2

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 55741-447-70

Habitrol®
 Nicotine Transdermal System Patch
 14 mg delivered over 24 hours
STOP SMOKING AID

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.

Habitrol®
 Nicotine Transdermal System Patch
 14 mg delivered over 24 hours
STOP SMOKING AID

14 mg
 Includes:
 Behavior Support Program with self-help guide

7 Patches
 (1 Week Kit)

The full course of treatment for STEP 2 is 2 or 6 weeks (depending on how many cigarettes you smoke per day); this package contains 7 patches (1 week course) only. Read the enclosed self-help guide for additional information.

Habitrol®
 Nicotine Transdermal System Patch
 14 mg delivered over 24 hours
STOP SMOKING AID

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

HABITROL® TAKE CONTROL™ SUPPORT PROGRAM

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



Principal Display Panel STEP 3

NDC 55741-446-74

Habitrol® Take Control™ Support Program
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)



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

Step 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	STEP 2	STEP 3
use one 21 mg patch/day	use one 14 mg patch/day	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 (not on hair)
- 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 lose 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 1-800-885-8882 Weekdays (9am-10pm ET) or visit us at www.habitrol.com

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 to vending machines or from any source where proof of age cannot be verified.

NDC 55741-446-70

Habitrol[®]
Nicotine Transdermal System Patch
7 mg delivered over 24 hours
STOP SMOKING AID

STEP 3

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.

Habitrol[®]

Nicotine Transdermal System Patch

7 mg delivered over 24 hours
STOP SMOKING AID

STEP 3

STEP 3

FOR USE AFTER COMPLETING STEP 2

7 mg

Includes:
Behavior Support Program with self-help guide

7 Patches
(1 Week Kit)

The full treatment course for STEP 3 is 14 patches (2 weeks); this package contains 7 patches (1 week course) only. Read the enclosed self-help guide for additional information.

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

NDC 55741-446-70



HABITROL STEP 1

nicotine transdermal system patch patch, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55741-448
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55741-448-74	14 in 1 CARTON	06/15/2019	

1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:55741-448-70	7 in 1 CARTON	06/15/2019	
2		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:55741-448-28	28 in 1 CARTON	07/01/2019	
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	07/13/2018	

HABITROL STEP 2

nicotine transdermal system patch patch, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55741-447
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55741-447-74	14 in 1 CARTON	04/22/2019	
1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:55741-447-70	7 in 1 CARTON	07/01/2019	
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	07/13/2018	

HABITROL STEP 3

nicotine transdermal system patch patch, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55741-446
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:55741-446-74	14 in 1 CARTON	06/15/2019	
1		24 h in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:55741-446-70	7 in 1 CARTON	07/01/2019	
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	07/13/2018	

Labeler - Dr. Reddy's Laboratories Inc. (802315887)