

NICOTINE TRANSDERMAL SYSTEM- nicotine patch, extended release
Target Corporation

Drug Facts

Active ingredient Step 1 (in each patch)

Nicotine, 21mg delivered over 24 hours

Active ingredient Step 2 (in each patch)

Nicotine, 14mg delivered over 24 hours

Active ingredient Step 3 (in each patch)

Nicotine, 7mg 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

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

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. Dispose of the used patches by folding sticky ends together. Replace in pouch and discard.

Directions

- **if you are under 18 years of age, ask a doctor before use**
- before using this product, read the enclosed User’s 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 according to the following 10 week schedule:

STEP 1	STEP 2	STEP 3
Use one 21mg patch/day	Use one 14mg patch/day	Use one 7mg patch/day
Weeks 1-6	Weeks 7-8	Weeks 9-10

- if you smoke **10 or less cigarettes per day**, do not use **STEP 1 (21mg)**. Start with **STEP 2 (14mg)** for 6 weeks, then **STEP 3 (7mg)** 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 chances of quitting successfully.
- apply one new patch every 24 hours on skin that is dry, clean and hairless. Save pouch for disposing of the patch after use.
- remove backing from patch and immediately press onto skin. Hold for 10 seconds.
- wash hands after applying or removing patch. Throw away the patch by folding sticky ends together. Replace in its pouch and discard. See enclosed User’s Guide for safety and handling.
- you may wear the patch for 16 or 24 hours.
- if you crave cigarettes when you wake up, wear the patch for 24 hours.
- if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning
- the used patch should be removed and a new one applied to a different skin site at the same time each day
- 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
- 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

ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between clear polyester backings

Questions or comments?

call toll-free **1-888-367-7919**

(English/Spanish) weekdays

Includes User's Guide with behavioral support program enrollment offer.

To increase your success in quitting:

- You must be motivated to quit.
- Complete the full treatment program, applying a new patch every day.
- Use with a support program as described in the enclosed User's Guide.
- **Not for sale to those under 18 years of age.**
- **Proof of age required.**
- **Not for sale in vending machines or from any source where proof of age cannot be verified.**

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

Read carton and enclosed User's Guide before using this product. Keep the carton and User's Guide. They contain important information

100% satisfaction guaranteed or your money back.

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Minneapolis, MN 55403

Shop Target.com

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What is the nicotine patch and how is it used?

The nicotine patch is a small, nicotine-containing patch. When you put on a nicotine patch, nicotine passes through the skin and into your body. The nicotine patch is very thin and uses special material to control how fast nicotine passes through the skin. Unlike the sudden jolts of nicotine delivered by cigarettes, the amount of nicotine you receive remains relatively smooth throughout the 24 or 16 hour period you wear the nicotine patch. This helps to reduce cravings you may have for nicotine.

READ THE LABEL

Principal Display Panel

NDC 11673-194-02

nicotine patch

nicotine transdermal system

21mg delivered over 24 hours

stop smoking aid

up & up™

14 PATCHES

Compare to the active ingredient in **NicoDerm® CQ®***

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**

STEP 1

14 CLEAR PATCHES (2-WEEK KIT)

ACTUAL SIZE

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30768XC

NDC 11673-194-02



nicotine patch

14
PATCHES

nicotine transdermal system
21 mg delivered over 24 hours
stop smoking aid

Compare to the active ingredient in NicoDerm® CQ®*

If you smoke more than 10 cigarettes per day, start with step 1
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STEP
1

ACTUAL SIZE

14 CLEAR PATCHES (2-WEEK KIT)

Principal Display Panel

NDC 11673-195-02

nicotine patch

nicotine transdermal system

14mg delivered over 24 hours

stop smoking aid

up & up™

14 PATCHES

Compare to the active ingredient in NicoDerm® CQ®*

If you smoke 10 or less cigarettes per day, start with step 2

If you smoke **more than 10 cigarettes** per day, start with **step 1**

STEP 2

14 CLEAR PATCHES (2-WEEK KIT)

ACTUAL SIZE

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30769XC

The image shows the principal display panel for the up&up nicotine patch. The packaging is white with blue accents. At the top left is the up&up logo, a blue arrow pointing up and to the right. To its right is the text "nicotine patch" in a large, bold, blue font. Below this, in a smaller blue font, is "nicotine transdermal system", "14 mg delivered over 24 hours", and "stop smoking aid". A box in the top right corner contains the number "14" and the word "PATCHES". Below the main text, there is a comparison to NicoDerm CQ and instructions on when to start with step 1 or step 2. A large blue chevron graphic points downwards. On the right side, a silver and blue graphic displays "STEP 2" in large blue numbers. At the bottom, it says "14 CLEAR PATCHES (2-WEEK KIT)" and "ACTUAL SIZE".

NDC 11673-195-02

up&up nicotine patch

nicotine transdermal system
14 mg delivered over 24 hours
stop smoking aid

Compare to the active ingredient in NicoDerm® CQ®*

If you smoke 10 or less cigarettes per day, start with step 2
If you smoke more than 10 cigarettes per day, start with step 1

STEP 2

ACTUAL SIZE

14 CLEAR PATCHES (2-WEEK KIT)

Principal Display Panel

NDC 11673-196-02

nicotine patch

nicotine transdermal system

7mg delivered over 24 hours

stop smoking aid

up & up™

14 PATCHES

Compare to the active ingredient in **NicoDerm® CQ®***

For use **after completing step 2**

STEP 3

14 CLEAR PATCHES (2-WEEK KIT)

ACTUAL SIZE

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NDC 11673-196-02



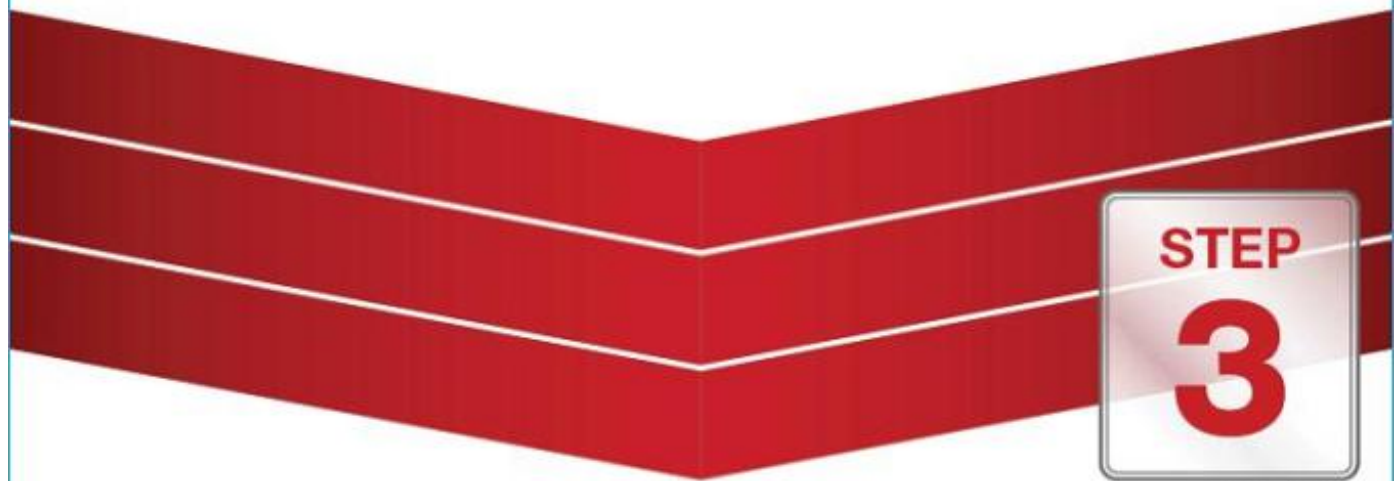
nicotine patch

14
PATCHES

nicotine transdermal system
7 mg delivered over 24 hours
stop smoking aid

Compare to the active ingredient in NicoDerm® CQ®*

For use after completing step 2



STEP
3

ACTUAL SIZE

14 CLEAR PATCHES (2-WEEK KIT)

NICOTINE TRANSDERMAL SYSTEM

nicotine patch, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-194
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
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ETHYLENE-VINYL ACETATE COPOLYMER (40% VINYL ACETATE) (UNII: L5F16ZG4ZU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-194-02	14 in 1 CARTON	02/16/2000	
1		24 h in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:11673-194-01	7 in 1 CARTON	02/16/2000	
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	NDA020165	02/16/2000	

NICOTINE TRANSDERMAL SYSTEM

nicotine patch, extended release

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Route of Administration	TRANSDERMAL		

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Ingredient Name	Strength
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:11673-195-02	14 in 1 CARTON	02/16/2000	
1		24 h in 1 PATCH; Type 2: Pre-filled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020165	02/16/2000	

NICOTINE TRANSDERMAL SYSTEM

nicotine patch, extended release

Product Information

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020165	02/16/2000	

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