

## **NICOTINE TRANSDERMAL SYSTEM- nicotine patch, extended release**

Sam's West Inc

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### **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.

#### **Do Not Use**

- if you continue to smoke, chew tobacco, use snuff, or use a nicotine gum 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. 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
- stop smoking completely when you begin using the patch
- **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 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg 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

- stop using the patch at the end of 10 weeks. If you started with **STEP 2**, 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***

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

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

call toll-free **1-866-255-5205** (English/Spanish) weekdays

### ***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.

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

Nicotine transdermal system 21 mg delivered over 24 hours

### ***Stop smoking aid***

- 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.

Free Audio CD upon request. See inside.

### ***What is the Nicotine Patch and How is it Used?***

Nicotine Patch is a small, nicotine-containing patch. When you put on a Nicotine Patch, nicotine passes through the skin and into your body. 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 carton and enclosed User's Guide before using this product. Keep the carton and User's Guide. They contain important information.

### **THE SIMPLY RIGHT™ PROMISE**

Simply Right is dedicated to providing healthful, gentle, and safe personal care products for the entire family. We continuously strive to be your trusted partner in wellness and exceed your expectations.

We would like to hear from you with any comments or suggestions. In the continental US or Canada, you can call us toll-free at 1-800-255-5205, Monday through Friday, from 8 am to 5 pm CST. Or you can send us an email at [samsclub.com](mailto:samsclub.com).

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Bentonville, AR 72716

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Made in Switzerland

**Send comments/questions to:**

**GCSP 5.4376.4C**

**Consumer Relations**

**P.O. Box 13398**

**Research Triangle Park, NC 27709-9627**

**Principal Display Panel**

**NDC 68196-194-03**

***nicotine patch***

Nicotine Transdermal System 21mg delivered over 24 hours **Stop smoking aid**

**21 mg**

**SIMPLY RIGHT™**

Health Care

*Compare to NicoDerm®CQ®\**

*Includes behavior support program enrollment form & user's 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

**step 1**

**21 clear patches**

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21 mg

**SIMPLY RIGHT™**   
Health Care

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## NICOTINE TRANSDERMAL SYSTEM

nicotine patch, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-194
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
ETHYLENE-VINYL ACETATE COPOLYMER (40% VINYL ACETATE) (UNII: L5F16ZG4ZU)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-194-03	21 in 1 CARTON	03/02/2012	
1		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	03/02/2012	

**Labeler** - Sam's West Inc (051957769)**Registrant** - sanofi-aventis U.S. LLC (011330557)