NICOTINE TRANSDERMAL SYSTEM STEP 1- nicotine patch, extended release NICOTINE TRANSDERMAL SYSTEM STEP 2- nicotine patch, extended release NICOTINE TRANSDERMAL SYSTEM STEP 3- nicotine patch, extended release Walgreens Company

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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.

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

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 1-4	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
- 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**

## Nicotine Transdermal System PATCH

21 mg delivered over 24 hours

## STOP SMOKING AID

Includes: Behavior Support Programwith 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



## **Principal Display Panel**

## NicotineTransdermalSystemPATCH

14 mg delivered over 24 hours

## **STOP SMOKING AID**

Includes: Behavior Support Programwith 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



## **Principal Display Panel**

#### **Nicotine Transdermal SystemPATCH**

7 mg delivered over 24 hours

#### **STOP SMOKING AID**

#### Includes: Behavior Support Program with self-help guide

#### STEP 3

FOR USE AFTER COMPLETING STEP 2



# NICOTINE TRANSDERMAL SYSTEM STEP 1

nicotine patch, extended release

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (So	ource)	NDC:03	863-0455(	NDC:43598-448)
Route of Administration	TRANS DERMAL					
Active Ingredient/Active	Molety					
Ingredi	ent Name		Basis	of Str	ength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NI	COTINE - UNII:6M3C89	OZY6R)	NICOTINE	E		21 mg in 24 h
lass stilles for one discusts						
Inactive Ingredients						
	Ingredient Name				S	Strength
Methacrylic Acid (UNII: 1CS02G8	656)					
Packaging						
# Item I Code	Package Descrip	tion		Marke Start D		Marketing End Date
						Lind Date

	Category	Citation	Date	Date
	Marketing	Application Number or Monogr	aph Marketing Start Date	_
Μ	1arketing	Information		
2		24 h in 1 PATCH; Type 2: Prefilled Drug Deliver Device/System (syringe, patch, etc.)	У	
2	NDC:0363- 0455-70	7 in 1 CARTON	09/01/2015	
1		24 h in 1 PATCH; Type 2: Prefilled Drug Deliver Device/System (syringe, patch, etc.)	У	
	0455-74	14 in 1 CARTON	09/01/2015	

nicotine patc	,					
Product In	formation					
Product Typ	e	HUMAN OTC DRUG	ltem Code (S	ource)	NDC:0363-045	7(NDC:43598-447)
Route of Ad	ministration	TRANS DERMAL				
Active Ingr	edient/Active	Moiety				
	Ingred	ient Name		Basis	of Strength	Strength
NICOTINE (UN	II: 6M3C89ZY6R) (N	IICOTINE - UNII:6M3C892	ZY6R)	NICOTINE	1	14 mg in 24 h
nactive In	aradiants					
	greatents					
Methacrylic A	cid (UNII: 1CS02G	Ingredient Name				Strength
	-	-				Strength
Packaging	-	-	ion		Marketing Start Date	Strength Marketing End Date
Packaging # Item Code	-	3656)	ion	9		Marketing
Packaging # Item Code NDC:0363- 0457-74	cid (UNII: 1CS02G 14 in 1 CARTON 24 h in 1 PATCH	3656)		9	Start Date	Marketing
Packaging # Item Code 1 NDC:0363- 0457-74	cid (UNII: 1CS02G 14 in 1 CARTON 24 h in 1 PATCH	B656) Package Descript Type 2: Prefilled Drug		9	Start Date	Marketing
Packaging # Item Code 1 NDC:0363- 0457-74	cid (UNII: 1CS02G 14 in 1 CARTON 24 h in 1 PATCH	B656) Package Descript		9	Start Date	Marketing
Packaging # Item Code 1 NDC:0363- 0457-74	cid (UNII: 1CS02G 14 in 1 CARTON 24 h in 1 PATCH; Device/System ( ng Information Applica	B656) Package Descript	Delivery	09/0 Market	<b>Start Date</b> 01/2015	Marketing

	otine patch	ı, exten	ded relea	ase				
Pr	oduct In	format	ion					
Pro	oduct Type	•		HUMAN OTC DRUG	ltem Code (	Source	) NDC:0363-04	151(NDC:43598-446
Ro	ute of Adr	ninistra	tion	TRANS DERMAL				
Ac	tive Ingr	edient/	Active	Moiety				
			Ingredi	ent Name		Ba	sis of Streng	th Strength
٩IC	OTINE (UNI	: 6M3C89	ZY6R) (NI	COTINE - UNII:6M3C8	9ZY6R)	NICO	TINE	7 mg in 24 h
na	active In	gredier						
Me	thacrylic Ad	id (UNII:		<b>ngredient Name</b> 556)				Strength
	thacrylic Ad	id (UNII:		•	•			Strength
Pa		: <b>id</b> (UNII:	1CS02G86	•			Marketing Start Date	Strength Marketing End Date
Pa #	ckaging Item	i <b>d</b> (UNII:	1CS02G86	556)				Marketing
Pa #	item Code	14 in 1 ( 24 h in 2	1CS02G86 F CARTON 1 PATCH; <sup>-</sup>	556)	otion		Start Date	Marketing
Pa #	item Code	14 in 1 ( 24 h in 2	1CS02G86 F CARTON 1 PATCH; <sup>-</sup>	Package Descrip	otion		Start Date	Marketing
<b>Pa</b> # 1	item Code	14 in 1 ( 24 h in 2 Device/S	1CS02G86 F CARTON 1 PATCH; <sup>-</sup> System (sy	Package Descrip Fype 2: Prefilled Druc ringe, patch, etc.)	otion		Start Date	Marketing
<b>Pa</b> # 1	<b>Item</b> Code NDC:0363- 0451-74	14 in 1 ( 24 h in 2 Device/S g Info	1CS02G86 F CARTON 1 PATCH; <sup>-</sup> System (sy Drmat	Package Descrip Fype 2: Prefilled Druc ringe, patch, etc.)	o <b>tion</b> g Delivery		Start Date	Marketing

Labeler - Walgreens Company (008965063)

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