

**NICOTINE TRANSDERMAL SYSTEM STEP 3- nicotine patch, extended release**  
**NICOTINE TRANSDERMAL SYSTEM STEP 2- nicotine patch, extended release**  
**NICOTINE TRANSDERMAL SYSTEM STEP 1- nicotine patch, extended release**  
**Chain Drug Consortium, LLC**

-----  
**NICOTINE TRANSDERMAL SYSTEM, STEP 1, STEP 2, STEP 3**

**Drug Fact**

***Active ingredient(in each patch)***

Step 1 - Nicotine, 21 mg delivered over 24 hours

Step 2 - Nicotine, 14 mg delivered over 24 hours

Step 3 - 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:**

Weeks 1 thru 2	Weeks 5 and 6	Weeks 7 and 8
Step 1	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, 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
- 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 °C – 25 °C (68 °F – 77 °F)

***Inactive ingredients***

acrylate adhesive, polyester, silicone adhesive

***Comments or Questions?***

**1-844-562-7963**

**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.

**PRINCIPAL DISPLAY PANEL - 7 mg CARTON**

Nicotine Transdermal System

NDC No. 68016-290-88

14 Patches



**PRINCIPAL DISPLAY PANEL - 14 mg CARTON**

Nicotine Transdermal System

NDC No. 68016-289-88

14 Patches

NDC 68016-289-88  
COMPARE TO THE ACTIVE INGREDIENT IN NASTRAL™



**STEP 3**

**CLEAR Nicotine Transdermal System Patch**

7 mg delivered over 24 hours  
**STOP SMOKING AID**

Includes Behavior Support Program with Self-Help Guide  
Free Audio CD upon request. See Self-Help Guide inside.

For use after completing Step 2

**7 mg**  
14 PATCHES



TradeMark is a registered trademark of Novartis Consumer Health, Inc.

**CLEAR 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 packaging. Do not use if individual patch is open or torn.

See bottom panel for lot number and expiration date.

Manufactured by:  
**AVEVA**  
Orion Corporation  
An APOTEC Company  
Millsboro, FL 33625

**Drug Facts**

**Active ingredient (in each patch)**  
Nicotine, 7 mg delivered over 24 hours

**Use** reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.

**Warnings**  
Do not use if pregnant or breastfeeding. Do not use this medicine on the advice of your health care provider. Smoking can seriously harm your child. This step involves not using any nicotine replacement medicine. This medicine is believed to be carbon monoxide. However, the risks to your child from this medicine are not known.  
Ask a doctor before use if you have:  
- High blood pressure not controlled with medication. Nicotine can increase your blood pressure.  
- Difficulty to adhesive tape or have skin problems, because you are more likely to get rashes.  
- Using a non-nicotine step 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 or chew tobacco while using the patch. The nicotine in your skin will be entering your bloodstream for several hours after you take off the patch.  
If you have mild dizziness 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.  
- Stronger heartbeats 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 patch 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:

Week 1 (quit day)	Weeks 2 and 3	Week 4 (end 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 8 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 patch 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.  
Do not wear more than one patch at a time.  
Do not cut patch in half or into smaller pieces.  
Do not use patch on the same skin site for more than 24 hours because it may irritate your skin and loses strength after 24 hours.  
It is important to continue treatment. 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, polyisobutylene adhesive.

**Questions or comments?** 1-844-666-3863

This product is not sold or used with Novartis Consumer Health, Inc.

**CLEAR Nicotine Transdermal System Patch**

7 mg delivered over 24 hours  
**STOP SMOKING AID**

**STEP 3**

- Not for sale to persons under 18 years of age.  
- Proof of age required.  
- Not for sale in vending machines if there are areas where proof of age cannot be verified.

CONTIBUTED BY  
CIVIAN DRUG CONSORTIUM  
3301 NW BOCA RATON BLVD  
SUITE 100  
BOCA RATON, FL 33431

MADE IN USA

If you receive one not controlled with this patch, please contact the manufacturer for a full refund.

PW 3002165 REV. 09/14



8 40986 02991 2



**PRINCIPAL DISPLAY PANEL- 21 mg CARTON**

Nicotine Transdermal System

NDC No. 68016-288-88

14 Patches



NICOTINE TRANSDERMAL SYSTEM STEP 3				
nicotine patch, extended release				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-290	
<b>Route of Administration</b>	TRANSDERMAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	7 mg in 24 h	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	DIMETHICONE (UNII: 92RU3N3Y1O)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68016-290-88	14 in 1 CARTON	10/20/1997	

1		1 in 1 POUCH		
1		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
ANDA	ANDA074612	10/20/1997	

## NICOTINE TRANSDERMAL SYSTEM STEP 2

nicotine patch, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-289
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
DIMETHICONE (UNII: 92RU3N3Y1O)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-289-88	14 in 1 CARTON	10/20/1997	
1		1 in 1 POUCH		
1		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
ANDA	ANDA074612	10/20/1997	

## NICOTINE TRANSDERMAL SYSTEM STEP 1

nicotine patch, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-288
<b>Route of Administration</b>	TRANSDERMAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	21 mg in 24 h

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68016-288-88	14 in 1 CARTON	10/20/1997	
1		1 in 1 POUCH		
1		24 h in 1 PATCH; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA074612	10/20/1997	

**Labeler** - Chain Drug Consortium, LLC (101668460)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aveva Drug Delivery Systems		783982093	manufacture(68016-288, 68016-289, 68016-290) , analysis(68016-288, 68016-289, 68016-290)

Revised: 2/2024

Chain Drug Consortium, LLC