

**NICOTINE TRANSDERMAL SYSTEM- nicotine transdermal system patch,  
extended release  
Topco Associates LLC**

-----

**Nicotine Transdermal System - nicotine patch, extended release**

**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 - 14 mg CARTON**

Nicotine Transdermal System

NDC No. 36800-034-14

14 Patches



## PRINCIPAL DISPLAY PANEL - 7 mg CARTON

Nicotine Transdermal System

NDC No. 36800-032-14

14 Patches



## PRINCIPAL DISPLAY PANEL- 21 mg CARTON

Nicotine Transdermal System

NDC No. 36800-038-14

14 Patches





## NICOTINE TRANSDERMAL SYSTEM

nicotine transdermal system patch, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-032
<b>Route of Administration</b>	TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Nicotine</b> (UNII: 6M3C89ZY6R) (Nicotine - UNII:6M3C89ZY6R)	Nicotine	7 mg in 24 h

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:36800-032-14	14 in 1 CARTON	08/25/2016	02/28/2023
1		1 h in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074612	08/25/2016	02/28/2023

### NICOTINE TRANSDERMAL SYSTEM

nicotine transdermal system patch, extended release

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-034
Route of Administration	TRANSDERMAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Nicotine</b> (UNII: 6M3C89ZY6R) (Nicotine - UNII:6M3C89ZY6R)	Nicotine	14 mg in 24 h

#### Inactive Ingredients

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

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-034-14	14 in 1 CARTON	08/25/2016	
1		1 h in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074612	08/25/2016	

### NICOTINE TRANSDERMAL SYSTEM

nicotine transdermal system patch, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-038
<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>
<b>1</b>	NDC:36800-038-14	14 in 1 CARTON	08/25/2016	11/30/2023
<b>1</b>		1 h in 1 POUCH; 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	08/25/2016	11/30/2023

**Labeler** - Topco Associates LLC (006935977)

**Registrant** - Aveva Drug Delivery Systems (783982093)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aveva Drug Delivery Systems, Inc		783982093	manufacture(36800-034, 36800-032, 36800-038) , analysis(36800-034, 36800-032, 36800-038)

Revised: 5/2023

Topco Associates LLC