

**NICOTINE TRANSDERMAL SYSTEM- nicotine trans dermal 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

5. Use patch with a behavioral support program, such as one described in the enclosed booklet.
 6. You may need to use the patch for a longer period to keep from smoking. Talk to your health care provider.
 7. Use one patch every 24 hours.
 8. Use one patch daily according to directions.
 9. You must be motivated to quit.
TO INCREASE YOUR SUCCESS IN QUITTING:

Drug Facts

Active ingredient (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 tapes or have skin problems because you are more likely to get rashes,
 • taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

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 bloodstream 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 patch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in trash.

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 4	Weeks 5 and 6	Weeks 7 and 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 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 patch to use for patch disposal. Dispose of the used patches by folding sticky ends together and putting in trash.
 • 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 20°C + 25°C (68°F + 77°F)

Inactive ingredients: acetate adhesive, polyester, silicone adhesive.

Comments or Questions? 1-844-662-7963

36800-038-14
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 300244 Rev. 08/18



NICOTINE TRANSDERMAL SYSTEM

nicotine transdermal system patch, extended release

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Nicotine (UNII: 6M3C89ZY6R) (Nicotine - UNII:6M3C89ZY6R)	Nicotine	7 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:36800-032-14	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				
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	
	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: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			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-038
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
Dimethicone (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-038-14	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	

Labeler - Topco Associates LLC (006935977)**Registrant** - Aveva Drug Delivery Systems (783982093)**Establishment**

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

Revised: 10/2018

Topco Associates LLC