

**NICOTINE TRANSDERMAL SYSTEM- nicotine transdermal system patch,
extended release
BluePoint Laboratories**

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.
- stomach ulcer or diabetes
- history of seizures

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

- 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.
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

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 4	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:

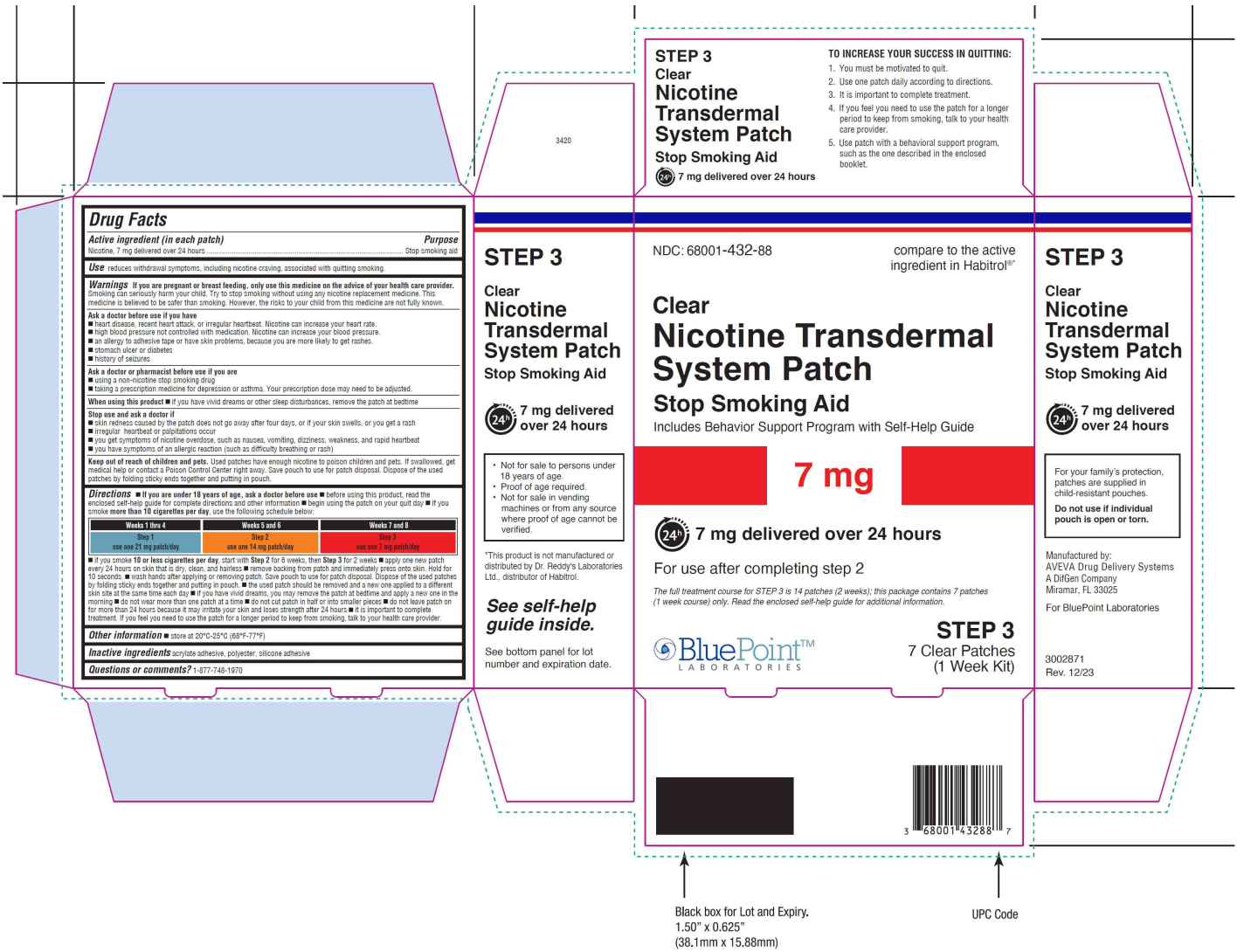
1. You must be motivated to quit.
2. Use one patch daily according to directions.
3. It is important to complete treatment.
4. If you feel you need to use the patch for a longer period to keep from smoking, talk to your health care provider.
5. Use patch with a behavioral support program such as the one described in the enclosed booklet.

PRINCIPAL DISPLAY PANEL -7 mg CARTON

Nicotine Transdermal System

NDC No. 68001-432-88

7 Patches



PRINCIPAL DISPLAY PANEL - 14 mg CARTON

Nicotine Transdermal System

NDC No.68001-433-88

7 Patches

STEP 3
Clear Nicotine Transdermal System Patch
Stop Smoking Aid
 7 mg delivered over 24 hours

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.

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 tape or have skin problems, because you are more likely to get rashes.
 ■ stomach ulcer or diabetes
 ■ history of seizures

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 ■ If you have vivid dreams or other sleep disturbances, remove the 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
 ■ you have symptoms of an allergic reaction (such as difficulty breathing or rash)

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 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 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

Questions or comments? 1-877-748-1970

STEP 3

Clear Nicotine Transdermal System Patch
Stop Smoking Aid

7 mg delivered over 24 hours

- 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.

See self-help guide inside.

See bottom panel for lot number and expiration date.

NDC: 68001-432-88

compare to the active ingredient in Habitrol®

Clear Nicotine Transdermal System Patch
Stop Smoking Aid

Includes Behavior Support Program with Self-Help Guide

7 mg

7 mg delivered over 24 hours

For use after completing step 2

The full treatment course for STEP 3 is 14 patches (2 weeks); this package contains 7 patches (1 week course) only. Read the enclosed self-help guide for additional information.

BluePoint
 LABORATORIES

STEP 3
 7 Clear Patches
 (1 Week Kit)

STEP 3

Clear Nicotine Transdermal System Patch
Stop Smoking Aid

7 mg delivered over 24 hours

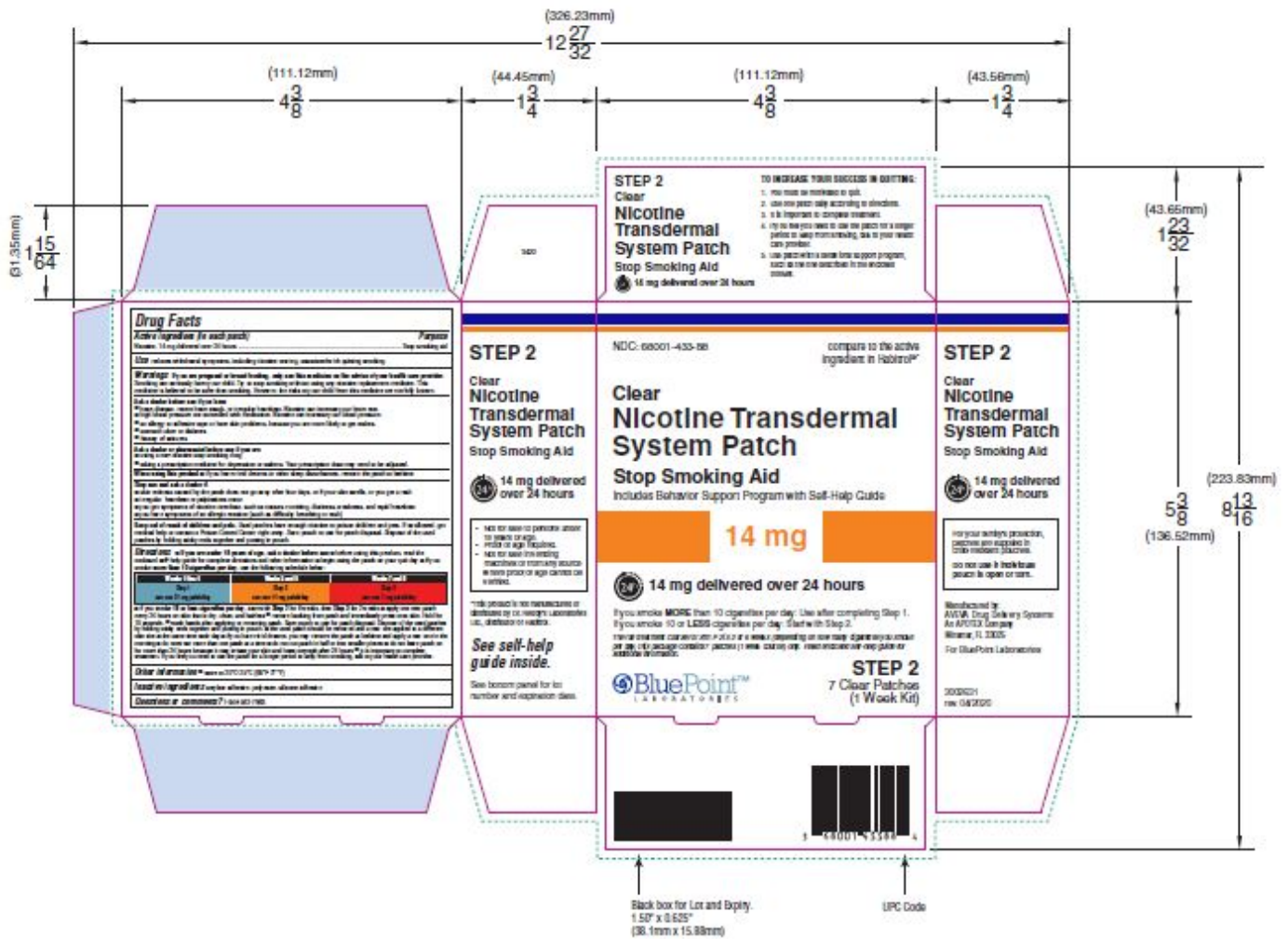
For your family's protection, patches are supplied in child-resistant pouches. Do not use if individual pouch is open or torn.

Manufactured by:
 AVEVA Drug Delivery Systems
 A DifGen Company
 Miramar, FL 33025
 For BluePoint Laboratories

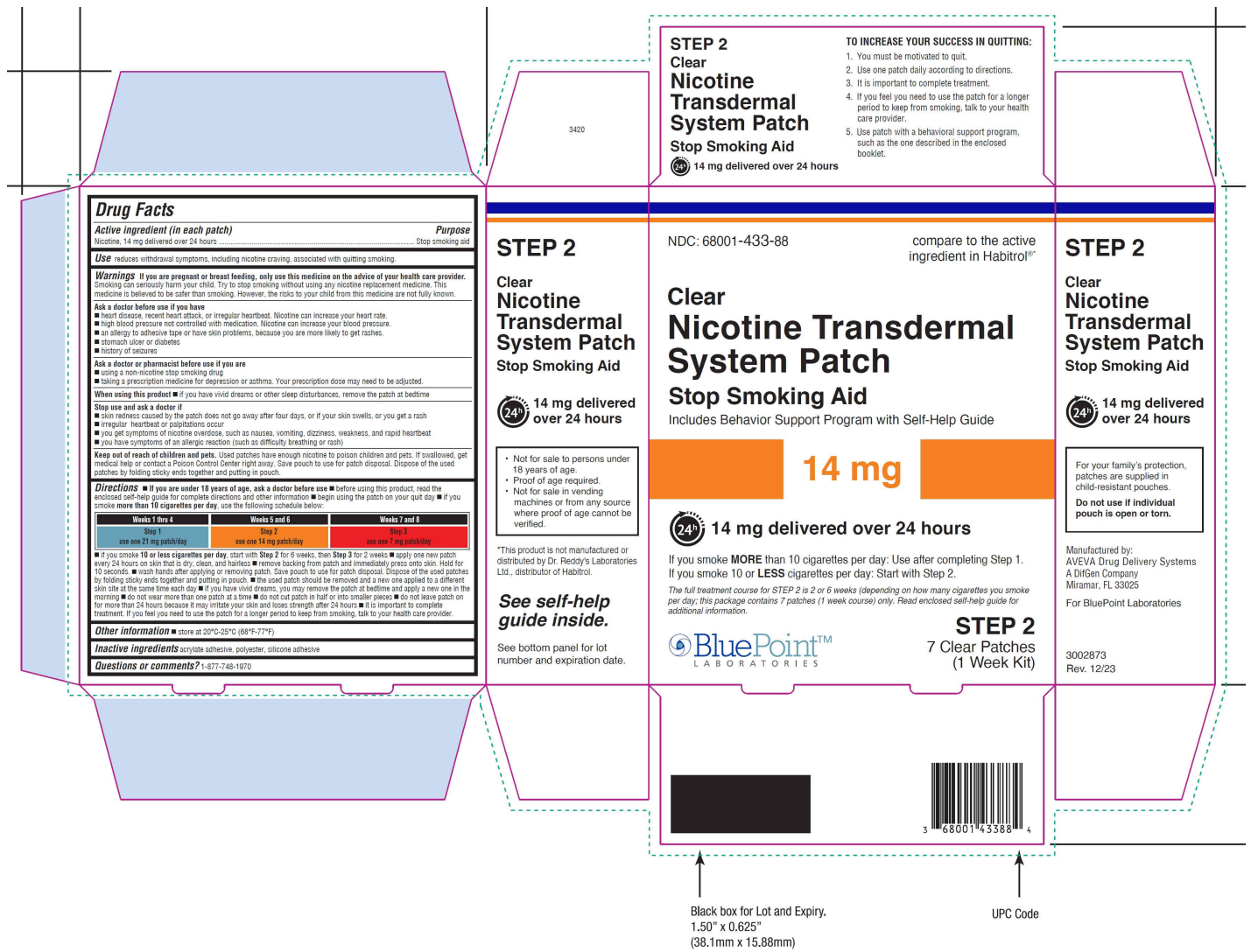
3002871
 Rev. 12/23

Black box for Lot and Expiry.
 1.50" x 0.625"
 (38.1mm x 15.88mm)

UPC Code



Nicotine Transdermal System
 NDC No.68001-433-88
 7 Patches Rev: 12-2023

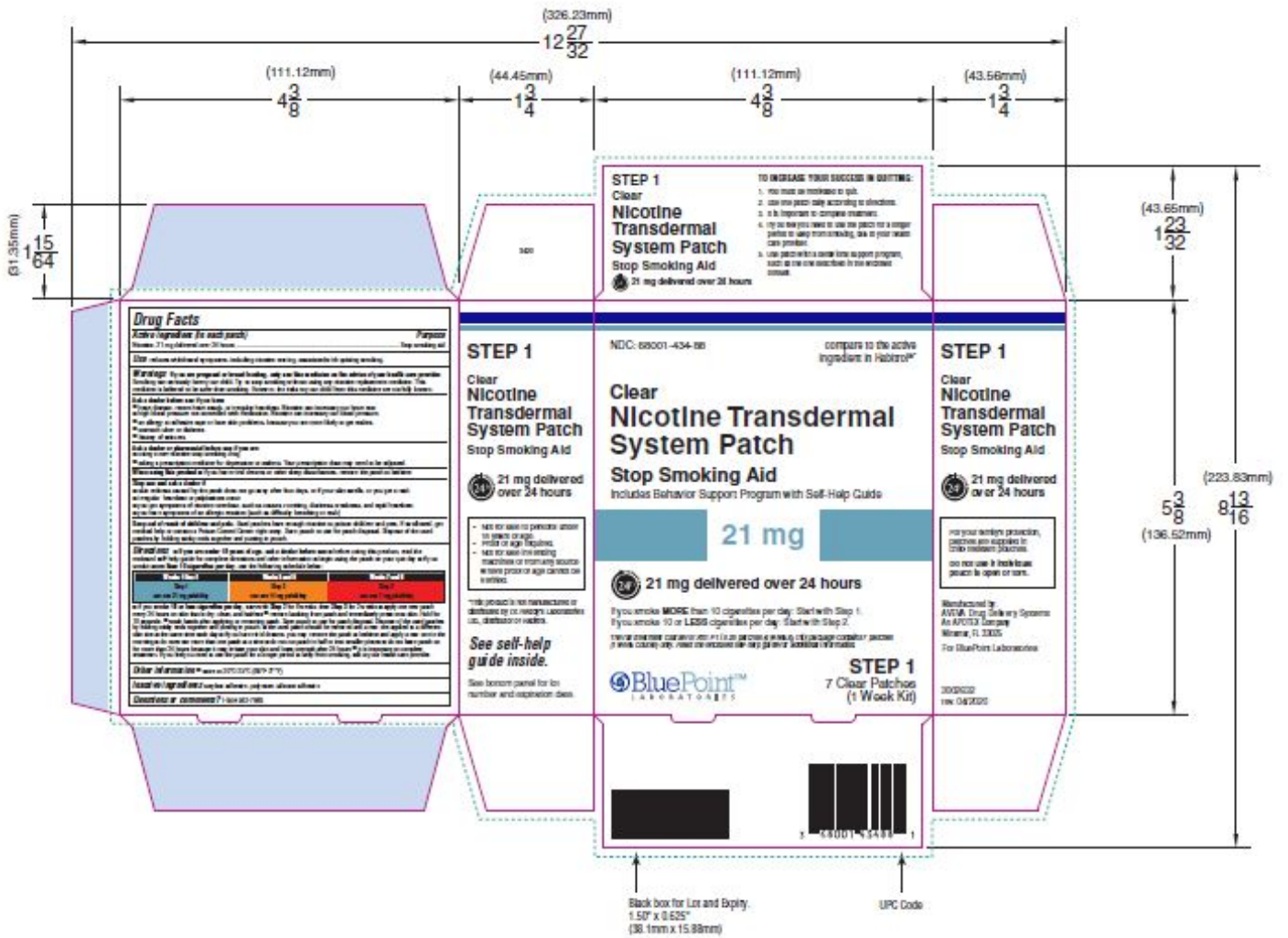


PRINCIPAL DISPLAY PANEL- 21 mg CARTON

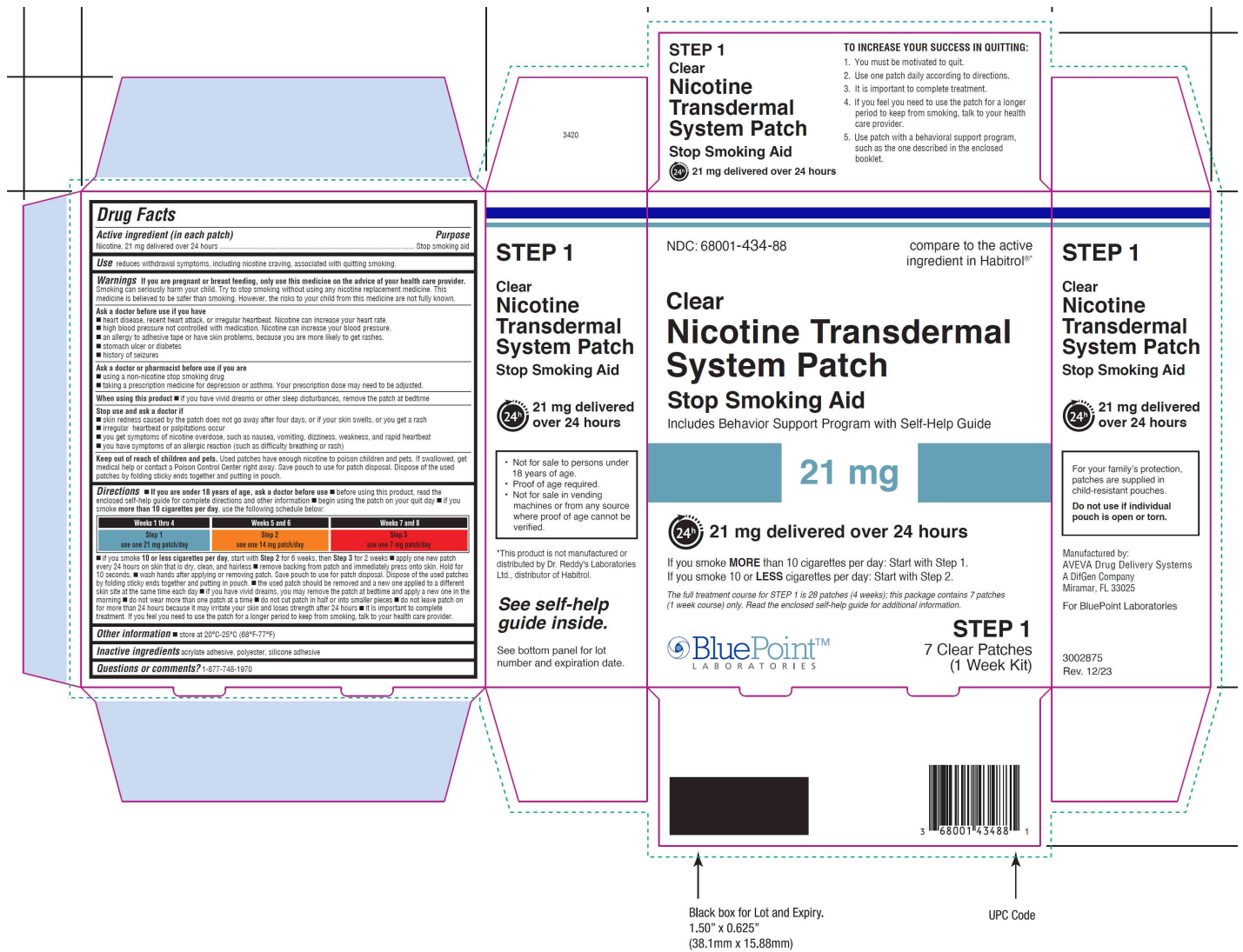
Nicotine Transdermal System

NDC No. 68001-434-88

7 Patches



Nicotine Transdermal System
NDC No. 68001-434-88
7 Patches Rev 12-2023



STEP 1
Clear Nicotine Transdermal System Patch
 Stop Smoking Aid
 24h 21 mg delivered over 24 hours

- 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.

Drug Facts

Active ingredient (in each patch) *Purpose*
 Nicotine 21 mg delivered over 24 hours 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.
- stomach ulcer or diabetes.
- history of seizures.

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 if you have vivid dreams or other sleep disturbances, remove the 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.
- you have symptoms of an allergic reaction (such as difficulty breathing or rash).

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 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 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 stores at 20°C-25°C (68°F-77°F)

Inactive ingredients sacrylate adhesive, polyester, silicone adhesive

Questions or comments? 1-877-748-1970

STEP 1
Clear Nicotine Transdermal System Patch
 Stop Smoking Aid

24h 21 mg delivered over 24 hours

- 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.

See self-help guide inside.
 See bottom panel for lot number and expiration date.

NDC: 68001-434-88 compare to the active ingredient in Habitrol®

Clear Nicotine Transdermal System Patch
 Stop Smoking Aid
 Includes Behavior Support Program with Self-Help Guide

21 mg

24h 21 mg delivered over 24 hours

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.

The full treatment course for STEP 1 is 28 patches (4 weeks); this package contains 7 patches (1 week course) only. Read the enclosed self-help guide for additional information.

BluePoint™
 LABORATORIES

STEP 1
 7 Clear Patches
 (1 Week Kit)

STEP 1
Clear Nicotine Transdermal System Patch
 Stop Smoking Aid

24h 21 mg delivered over 24 hours

For your family's protection, patches are supplied in child-resistant pouches. Do not use if individual pouch is open or torn.

Manufactured by:
 AVEVA Drug Delivery Systems
 A DivGen Company
 Miramar, FL 33025
 For BluePoint Laboratories

3002875
 Rev. 12/23



Black box for Lot and Expiry.
 1.50" x 0.625"
 (38.1mm x 15.88mm)

UPC Code

NICOTINE TRANSDERMAL SYSTEM

nicotine transdermal system patch, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-432
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:68001-432-88	7 in 1 CARTON	06/22/2020	
1		1 h in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:68001-432-90	14 in 1 CARTON	06/22/2020	
2		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	06/22/2020	

NICOTINE TRANSDERMAL SYSTEM				
nicotine transdermal system patch, extended release				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-434	
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:68001-434-88	7 in 1 CARTON	06/22/2020	
1		1 h in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:68001-434-90	14 in 1 CARTON	06/22/2020	
2		1 h in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:68001-434-91	28 in 1 CARTON	06/22/2020	

3	1 h in 1 POUCH; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074612	06/22/2020	

NICOTINE TRANSDERMAL SYSTEM

nicotine transdermal system patch, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-433
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:68001-433-88	7 in 1 CARTON	06/22/2020	
1		1 h in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:68001-433-90	14 in 1 CARTON	06/22/2020	
2		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	01/11/2019	

Labeler - BluePoint Laboratories (985523874)

Registrant - Aveva Drug Delivery Systems (783982093)

Establishment

Name	Address	ID/FEI	Business Operations
Aveva Drug Delivery Systems		783982093	analysis(68001-432, 68001-433, 68001-434) , manufacture(68001-432, 68001-433, 68001-434)

Revised: 6/2024

BluePoint Laboratories