

**MEDLINE- nicotine patch**  
**Medline Industries, LP**

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**191/2/3 Nicotine Transdermal Patch**

***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 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, or 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:



- 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

## **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.

## **Manufacturing Information**

[www.medline.com](http://www.medline.com)

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Manufactured for: Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA

Manufactured by: Aveva Drug Delivery Systems, Inc., A DifGen Company, Miramar, FL 33025

Made in USA of Foreign and Domestic Materials

1-800-MEDLINE

REF: OTCM019285; OTCM019189; OTCM019389

## **Package Labels**

**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, or 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.



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 find you need to use the patch for a longer period to help 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?** 1-877-746-1970



Clear  
**Nicotine Transdermal Patch System**

24 hour time release  
Stop smoking aid



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

NDC 32229-056-89



Clear  
**Nicotine Transdermal Patch System**

24 hour time release

Stop smoking aid  
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.

**14** Patches | 21 mg  
Includes Behavior Support Program and a User Manual

REF OTCM019285

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 Manufactured for: Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA.  
 Manufactured by: Avera Drug Delivery Systems, Inc., A Cipla Company, Midland, FL 32025.  
 Made in USA of Foreign and Domestic Materials. 1-800-MEDLINE, VA 650-4191.



**Nicotine Transdermal Patch System**  
 Clear  
 For more information, visit our website at www.medline.com. ©2024 Medline Industries, LP. All rights reserved. NDC 32229-056-89. 14 Patches | 21 mg. Includes Behavior Support Program and a User Manual. Stop smoking aid. 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. Do not use if individual patch is open or torn. For your family's protection, patches are supplied in child-resistant pouches. 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 find you need to use the patch for a longer period to help from smoking, talk to your health care provider. 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, or have an allergy to adhesive tape or skin problems. Ask a doctor before use if you have heart disease, recent heart attack, or irregular heartbeat. 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. Use: reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking. 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: Weeks 1 thru 4, use one 21 mg patch per day. Step 2: Weeks 5 and 6, use one 14 mg patch per day. Step 3: Weeks 7 and 8, use one 7 mg patch per 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 find you need to use the patch for a longer period to help 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? 1-877-746-1970.



Clear  
**Nicotine Transdermal Patch System**

14 Patches



Step 1  
21 mg

Step 1  
21 mg

Step 1  
21 mg

### Drug Facts

**Active ingredient (in each patch)** **Purpose**  
Nicotine, 14 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 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, or 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 rolling 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.



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 rolling 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 lose strength after 24 hours. It is important to complete treatment. If you need to use the patch for a longer period to help from smoking, talk to your health care provider.

**Other information** Store at 20°C to 25°C (68°F to 77°F)

**Inactive ingredients** acrylics adhesive, polyester, silicone adhesive

**Questions or comments?** 1-877-748-1870



## Clear Nicotine Transdermal Patch System

24 hour time release  
Stop smoking aid

Step 2  
14 mg

Use after completing STEP 1

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

NDC 32229-191-89



## Clear Nicotine Transdermal Patch System

24 hour time release

Stop smoking aid  
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.

**14** Patches | 14 mg | Use after completing STEP 1  
Includes Behavior Support Program and a User Manual

REF OTCM019189

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Manufactured for: Medline Industries, LP, Three Lakes Drive, Northfield, IL 60092 USA.  
Manufactured by: Avera Drug Delivery Systems, Inc., A Dillien Company, Miramar, FL 33025.  
Made in USA of Foreign and Domestic Materials. 1-800-MEDLINE, V4 R124PH.



- To receive your success in quitting, you must be motivated to quit.
- 1 You must be motivated to quit.
  - 2 Use one patch daily, according to directions.
  - 3 Do not smoke or drink alcohol.
  - 4 If you rely on or feel you need the patch for a longer period, keep from smoking, talk to your health care provider.
  - 5 Use patches with a behavior change program, such as one described in the enclosed self-help guide.

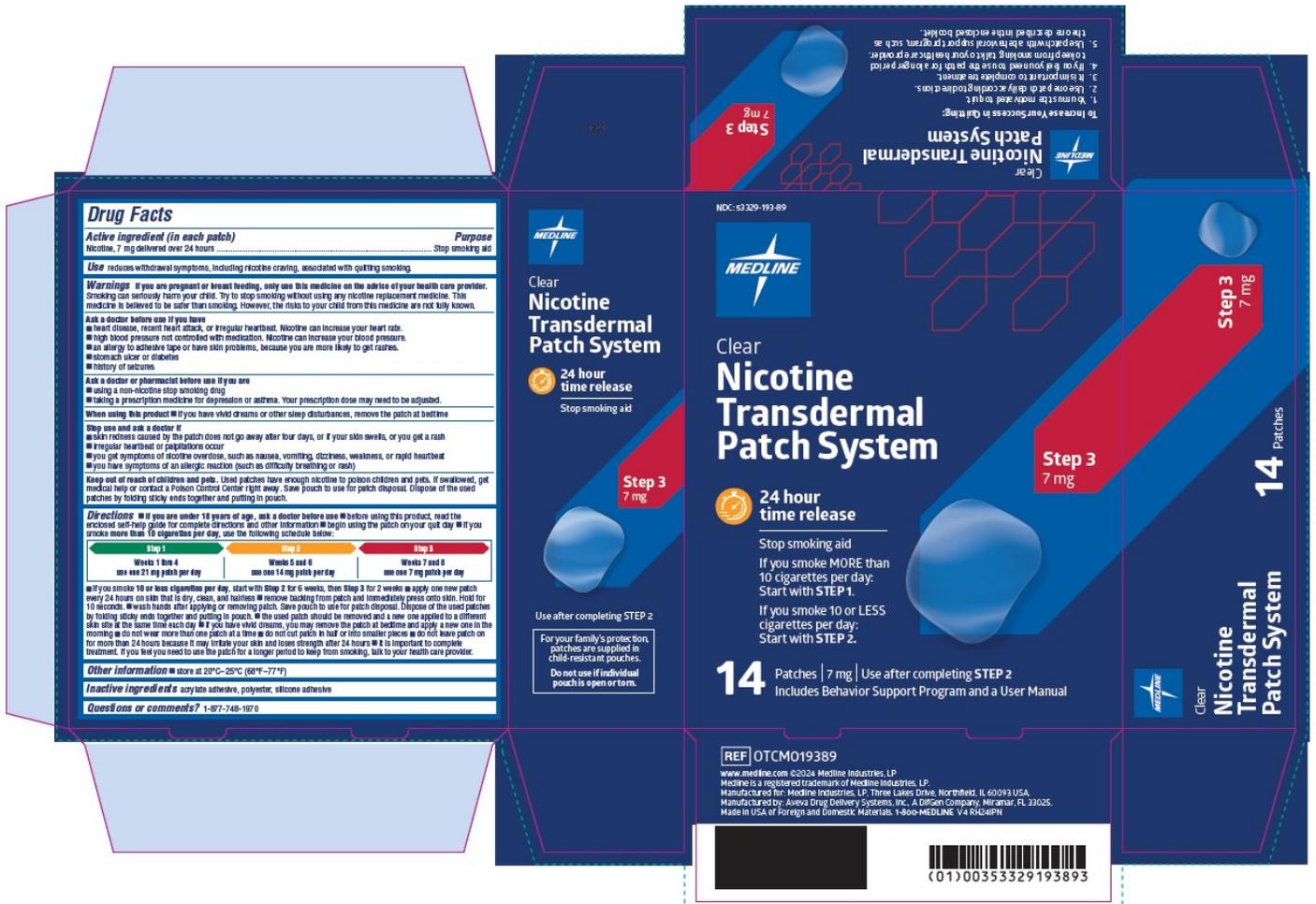
Clear Nicotine Transdermal Patch System



Clear Nicotine Transdermal Patch System

14 Patches

Step 2  
14 mg



## MEDLINE nicotine patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-193
<b>Route of Administration</b>	TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	7 mg

### Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:53329-193			

1	NDC:53329-193-89	14 in 1 CARTON	08/28/2022	
1	NDC:53329-193-09	1 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	ANDA074645	06/30/2022	

## MEDLINE

nicotine patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-192
Route of Administration	TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	21 mg

### Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-192-89	14 in 1 CARTON	08/28/2022	
1	NDC:53329-192-09	1 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	06/30/2022	

## MEDLINE

nicotine patch

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-191
<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	14 mg

**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:53329-191-89	14 in 1 CARTON	08/28/2022	
1	NDC:53329-191-09	1 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	ANDA074611	06/30/2022	

**Labeler** - Medline Industries, LP (025460908)**Registrant** - Medline Industries, LP (025460908)