

MEDLINE- nicotine patch
Medline Industries, LP

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?

- 1-844-562-7963

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.

Manufacturing Information

Manufactured for:

Medline Industries, LP

Three Lakes Drive

Northfield, IL 60093 USA

Manufactured by:

Apotex Corp.

2400 N Commerce Pkwy

Weston, FL 33326

Made in USA of Foreign and Domestic Materials

www.medline.com

1-800-MEDLINE (633-5463)

REF: OTCM019285; OTCM019189; OTCM019389

V3 RI22AOE

Package Labels

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 tapes 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:
 ■ taking a non-nicotine drug for smoking cessation
 ■ 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 rashes 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:

Step 1	Step 2	Step 3
Weeks 1 thru 4 use one 21 mg patch per day	Weeks 5 and 6 use one 14 mg patch per day	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 4 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, with 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 have 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 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? 1-844-512-7963

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 5329-191-89



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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 Made in USA of Foreign and Domestic Materials. 1400-MEDLINE V3 R123AC

LOT
 Expiration Date: YYYY-MM-DD



Nicotine Transdermal Patch System
 Clear
 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 a longer period of treatment.
 4. If you feel you need to use the patch for a longer period, keep from smoking, talk to your health care provider.
 5. Use it with a behavioral quit program, such as the one described in the enclosed booklet.

Step 2
 14 mg

Step 2
 14 mg

Step 2
 14 mg

14 Patches



Clear Nicotine Transdermal Patch System

Drug Facts

Active ingredient (in each patch) Nicotine, 21 mg delivered over 24 hours **Purpose** Stop smoking aid

Use reduce 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.

Take 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.
- recent use of 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

- withdrawal symptoms 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 patch by folding sticky ends together and putting in pouch.

Directions If you are under 18 years of age, ask a doctor before use. If you are using this product, read the enclosed self-help guide for complete directions and other information on using the patch on your quit day. If you smoke more than 10 cigarettes per day, use the following schedule below:

Step 1	Step 2	Step 3
Weeks 1 and 4 use one 21 mg patch per day	Weeks 5 and 6 use one 14 mg patch per day	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 1 week, 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. 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 believe 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, polymer, silicone adhesive

Questions or comments? 1-844-562-7963



Clear
**Nicotine
Transdermal
Patch System**

24 hour
time release
Stop smoking aid

Step 1
21 mg

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

NDC 5329-492-89



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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Made in USA of Foreign and Domestic Materials. 1-800-MEDLINE Y3 R12ZACC

LOT

Expiration Date: YYYY-MM-DD



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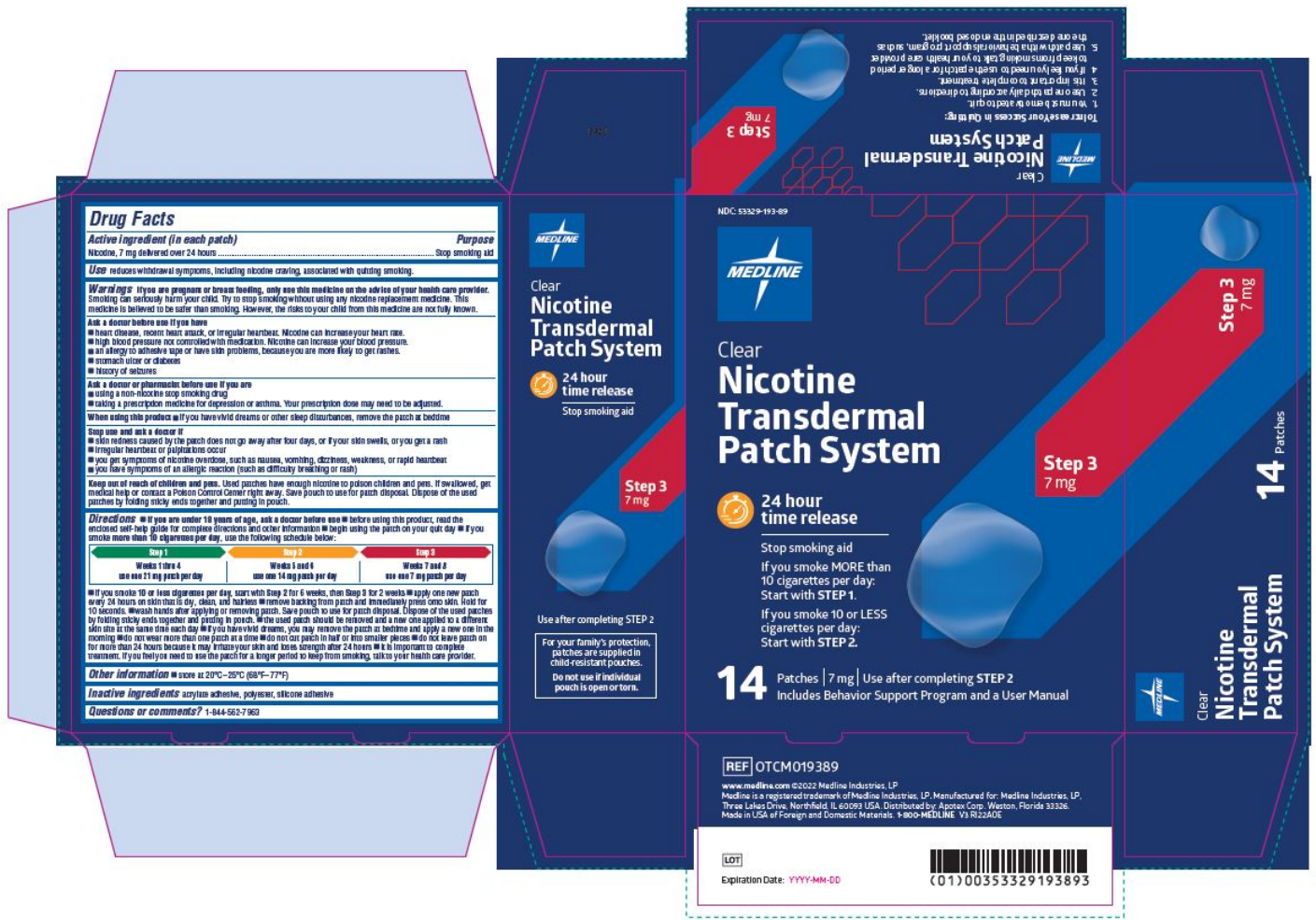
To increase your success in quitting:
1. You must be motivated to quit.
2. Use one patch daily according to directions.
3. It is important to complete treatment.
4. If you feel tired or stressed, try to get a good night's sleep.
5. Use patch with a behavioral support program, such as the one described in the enclosed booklet.

Step 1
21 mg

14 Patches

Clear
**Nicotine
Transdermal
Patch System**





MEDLINE nicotine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-193
Route of Administration	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

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-191
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	14 mg

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074611	06/30/2022	

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 7/2023

Medline Industries, LP