

NICOTINE- nicotine patch
Strategic Sourcing Services LLC

Nicotine Transdermal System

Drug Facts

Active ingredient Step One (in each patch)

Nicotine, 21 mg delivered over 24 hours

Active ingredient Step Two (in each patch)

Nicotine, 14 mg delivered over 24 hours

Active ingredient Step Three (in each patch)

Nicotine, 7 mg delivered over 24 hours

Purpose

Stop smoking aid

Uses

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 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 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 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 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**
- 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 used patch 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 - STEP ONE 21 mg CARTON

Principal Display Panel - Step 1 – 21 mg Carton Label

McKesson SunMark®

NDC 70677-0032-1

COMPARE TO THE ACTIVE INGREDIENT IN HABITROL®*

Clear

Nicotine

Transdermal System

21 mg delivered over 24 hours

STOP SMOKING AID

21 mg

Includes Behavior Support Program with Self-Help Guide

STEP ONE

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

*Habitrol® is a registered trademark of Novartis Consumer Health, Inc.



PRINCIPAL DISPLAY PANEL - STEP TWO 14 mg CARTON

Principal Display Panel - Step 2 – 14 mg Carton Label

McKesson SunMark®

NDC 70677-0031-1

COMPARE TO THE ACTIVE INGREDIENT IN HABITROL®*

Clear

Nicotine

Transdermal System

14 mg delivered over 24 hours

STOP SMOKING AID

14 mg

Includes Behavior Support Program with Self-Help Guide

STEP ONE

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

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PRINCIPAL DISPLAY PANEL - STEP THREE 7 mg CARTON

Principal Display Panel - Step 3 – 7 mg Carton Label

McKesson SunMark®

NDC 70677-0030-1

COMPARE TO THE ACTIVE INGREDIENT IN HABITROL®*

Clear

Nicotine

Transdermal System

7 mg delivered over 24 hours

STOP SMOKING AID

7 mg

Includes Behavior Support Program with Self-Help Guide

STEP ONE

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

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NICOTINE

nicotine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0030
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:70677-0030-1	14 in 1 CARTON	12/04/2017	
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	12/04/2017	

NICOTINE

nicotine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0031
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:70677-0031-1	14 in 1 CARTON	12/04/2017	
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	12/04/2017	

NICOTINE

nicotine patch

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0032
Route of Administration		TRANSDERMAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
NICO TINE (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:70677-0032-1	14 in 1 CARTON	12/04/2017	
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	12/04/2017	

Labeler - Strategic Sourcing Services LLC (116956644)