

NICOTINE TRANSDERMAL PATCHES- aroamas nicotine transdermal patches - stop smoking aid patch
Ehy Holdings LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

81799-002

Nicotine Transdermal Patches

Active Ingredient(s)

Nicotine 6%.....Stop smoking aid
menthol 0.3%.....Stop smoking aid

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 healthcare 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 an over-the-counter nicotine stop smoking drug

*taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted

Do not use

- *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

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 wells, 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

STEP 1	STEP 2	STEP 3
Use one 21mg patch/day	Use one 14mg patch/day	Use one 7mg patch/day
Weeks 1-6	Weeks 7-8	Weeks 9-10

*If you smoke 10 or less cigarettes per day, do not use Step 1 (21mg). Start with Step 2 (14mg) for 6 weeks, then Step 3 (7mg) for 2 weeks and then stop.

*apply one new patch every 24 hours on skin that is dry, clean and hairless.

*remove backing from patch and immediately press on to 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.

*you may wear the patch for 18 to 24 hours

*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

*to avoid possible burns, remove patch before undergoing and MR(magnetic resonance imaging) procedures

*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 healthcare provider.

Other information

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.

Inactive ingredients

codonopsis pilosula, chrysanthemum, clove, natural tobacco

Package Label - Principal Display Panel

81799-002-01 7mg 1Patch 21PATCH 1BOX

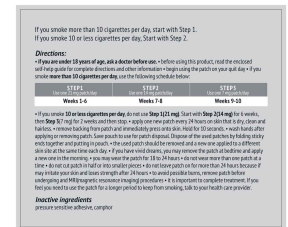


Inner Pack Size: 90x75mm

Front



Back



NICOTINE TRANSDERMAL PATCHES

aroamas nicotine transdermal patches - stop smoking aid patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81799-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.3 mg in 100 mg
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	6 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
CHRYSANTHEMUM INDICUM FLOWER (UNII: I6OER6U04L)	
CLOVE (UNII: K48IKT5321)	
CODONOPSIS PILOSULA WHOLE (UNII: 76AI4Q0335)	
TOBACCO LEAF (UNII: 6YR2608RSU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81799-002-01	21 in 1 BOX	03/30/2020	
1		7 mg in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/30/2020	

Labeler - Ehy Holdings LLC (117322715)

Establishment

Name	Address	ID/FEI	Business Operations
Ehy Holdings LLC		117322715	manufacture(81799-002)

Revised: 1/2023

Ehy Holdings LLC