

NICOTINE POLACRILEX- nicotine polacrilex gum, chewing
Rite Aid Corporation

Nicotine Polacrilex Gum Coated Ice Mint 4 mg ANDA204833 - Equate

Drug Facts

Active ingredient (in each chewing piece)

Nicotine Polacrilex 4 mg (nicotine)

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

- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- 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.

Stop use and ask a doctor if

- mouth, teeth, or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, 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.

Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- **if you are under 18 years of age, ask a doctor before use**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the gum on your quit day
- **if you smoke your first cigarette more than 30 minutes after waking up,** use 2 mg nicotine gum
- **if you smoke your first cigarette within 30 minutes of waking up,** use 4 mg nicotine gum according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

Other information

- **each piece contains:** calcium 115 mg, sodium 11 mg

- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients

acacia, acesulfame potassium, butylated hydroxytoluene, carnauba wax, FD&C red #40, gum base, hydroxypropyl cellulose, hypromellose, natural and artificial, cinnamon flavors, sodium bicarbonate, sodium carbonate, talc, titanium dioxide and xylitol.

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient of Nicorette® Gum*

FREE | SUGAR

FROM | FREE

Nicotine Gum

Nicotine Polacrilex Gum USP,

4 mg (nicotine)

Stop Smoking Aid

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP

If you smoke your first cigarette MORE THAN 30 MINUTES after waking up, use Nicotine Polacrilex gum, 2 mg

Sugar free coated nicotine gum

COATED CINNAMON FLAVOR

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivate to quit
2. Use Enough - Chew at least 9 pieces of Nicotine Polacrilex Gum per day during the first six weeks
3. Use long enough - Use Nicotine Polacrilex Gum for the full 12 weeks
4. Use with a Support Program as directed in the enclosed User's Guide

To remove the gum, tear off single unit

Peel off backing starting at corner with loose edge

Push gum through foil

- not for sale to those 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

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® Gum

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE OPEN OR TORN.

DISTRIBUTED BY:

RITE AID 30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

Package Label

Drug Facts (continued)

Other information

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- store at 20-25°C (68 -77°F)
- protect from light

Inactive ingredients

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Questions or comments?
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Monday-Friday 9AM-5PM EST

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TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough** - Chew at least **9 pieces** of Nicotine Polacrilex Gum per day during the first six weeks.
3. **Use Long Enough** - Use Nicotine Polacrilex Gum for the full 12 weeks.
4. **Use With a Support Program** as directed in the enclosed User's Guide.

NDC 11822-2128-3

FREE FROM SUGAR FREE

Compare to the active ingredient in **Nicorette® Gum***

Nicotine Gum

4 mg

Nicotine Polacrilex Gum USP, 4 mg (nicotine)
Stop Smoking Aid

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicotine Polacrilex Gum USP, 2 mg

sugar free coated nicotine gum



ACTUAL SIZE COATED CINNAMON FLAVOR



20

PIECES 4 mg EACH

SATISFACTION GUARANTEE
If you're not satisfied, we'll happily refund your money.

THIEF SURVEILLANCE TAG AREA

DISTRIBUTED BY:
RITE AID, 30 HUNTER LANE,
CAMP HILL, PA 17011
www.riteaid.com

BLISTER PACKAGED FOR YOUR PROTECTION. SEAL IS BROKEN IF OPEN OR TORN.

- not for sale to those 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



Push gum through foil.



Peel off backing starting at corner with loose edge.



To remove the gum, tear off single unit.



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Drug Facts

Active ingredient (in each chewing piece) **Purpose**

Nicotine polacrilex.....4 mg (nicotine).....Stop smoking aid

Use ■ reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

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- a sodium-restricted diet ■ heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- 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.

Stop use and ask a doctor if

- mouth, teeth, or jaw problems occur ■ irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat ■ oral blistering occurs
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

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- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

RITE AID Nicotine Gum Coated Cinnamon Flavor

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-2128
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)		NICOTINE	4 mg	
Inactive Ingredients				
Ingredient Name			Strength	
ACACIA (UNII: 5C5403N26O)				
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SODIUM CARBONATE (UNII: 45P3261C7T)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
XYLITOL (UNII: VCQ006KQ1E)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
Product Characteristics				
Color	pink (Dark)	Score	no score	
Shape	SQUARE	Size	14mm	
Flavor	CINNAMON	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-2128-4	100 in 1 CARTON	01/31/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-2128-3	20 in 1 CARTON	01/31/2020	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA079219	01/31/2020	

Labeler - Rite Aid Corporation (014578892)

