NICOTINE POLACRILEX- nicotine polacrilex gum, chewing Rite Aid Corporation

Nicotine Polacrilex Coated Ice Mint 2 mg and 4 mg - Leader

Drug Facts

Active ingredient (in each chewing piece) - 2 mg

Nicotine polacrilex 2 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 - 2 mg

- 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 within 30 minutes of waking up, use 4 mg nicotine gum
- if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine gum according to the following 12 week schedule:

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

• each piece contains: calcium 115 mg, sodium 8 mg

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

Inactive ingredients - 2 mg

acacia, acesulfame potassium, carnauba wax, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, 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 - 2 mg

Compare to the active ingredient of Nicorette® Gum*

FREE | SUGAR

FROM | FREE

Nicotine Gum

Nicotine Polacrilex Gum USP,

2 mg (nicotine)

Stop Smoking Aid

TO INCREASE YOUR SUCCESS IN QUITTING:

- You must be motivated to quit.
- **Use Enough** Chew **at least 9 pieces** of Nicotine Polacrilex Gum per day during the first six weeks.
- **Use Long Enough** Use Nicotine Polacrilex Gum for the full 12 weeks.
- 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

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP

If you smoke your first cigarette <u>WITHIN</u> 30 MINUTES of waking up, use Nicotine Polacrilex Gum, 4 mg

sugar free coated nicotine gum

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEAL ARE 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.

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

DISTRIBUTED BY:

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

Package label



Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (nicotine) Stop Smoking Aid

you're not satisfied, u apply refund your mo SATISFACTION

RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011 DISTRIBUTED BY:

"This product is not manufactured or distributed by GlassoSmithkline Consumer Healthcare, L.P., distributor of Nicoretto* Gum.

Crit 1-817-753-3935 Monday-Friday 944-5FM EST

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Directions:

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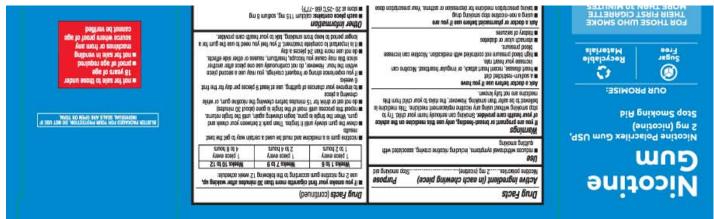
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RITE AID Nicotine Gum Coated Ice Mint

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-3313

Route of Administration BUCCAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) NICOTINE 2 mg

Inactive Ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N260)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics				
Color	white	Score	no score	
Shape	SQUARE	Size	14mm	
Flavor	MINT (ice)	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822- 3313-8	160 in 1 CARTON	01/31/2020	01/31/2027
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822- 3313-9	20 in 1 CARTON	01/31/2020	01/31/2027
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11822- 3313-6	100 in 1 CARTON	01/31/2020	01/31/2027
3		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	ANDA204794	01/31/2020	01/31/2027	

Labeler - Rite Aid Corporation (014578892)

Revised: 11/2025 Rite Aid Corporation