

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 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 - 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 WITHIN 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

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.



To remove the gum, tear off single unit.



Peel off backing starting at corner with loose edge.



Push gum through foil.

FREE | **SUGAR**
FROM | **FREE**

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

Nicotine Gum

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

2 mg

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

If you smoke your first cigarette WITHIN 30 MINUTES of waking up, use Nicotine Polacrilex Gum USP, 4 mg

sugar free coated nicotine gum



ACTUAL SIZE
COATED
ICE MINT
FLAVOR

100
PIECES 2 mg EACH

FREE | **SUGAR**
FROM **FREE**

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

Nicotine Gum

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

2 mg

SATISFACTION
GUARANTEE

www.riteaid.com

DISTRIBUTED BY:
RTE AID, 30 HUNTER LANE,
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inactive ingredients: acacia, ascorbate potassium, carnation wax, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium hydroxide, sodium carbonate, talc, titanium dioxide, xanthan

project now left

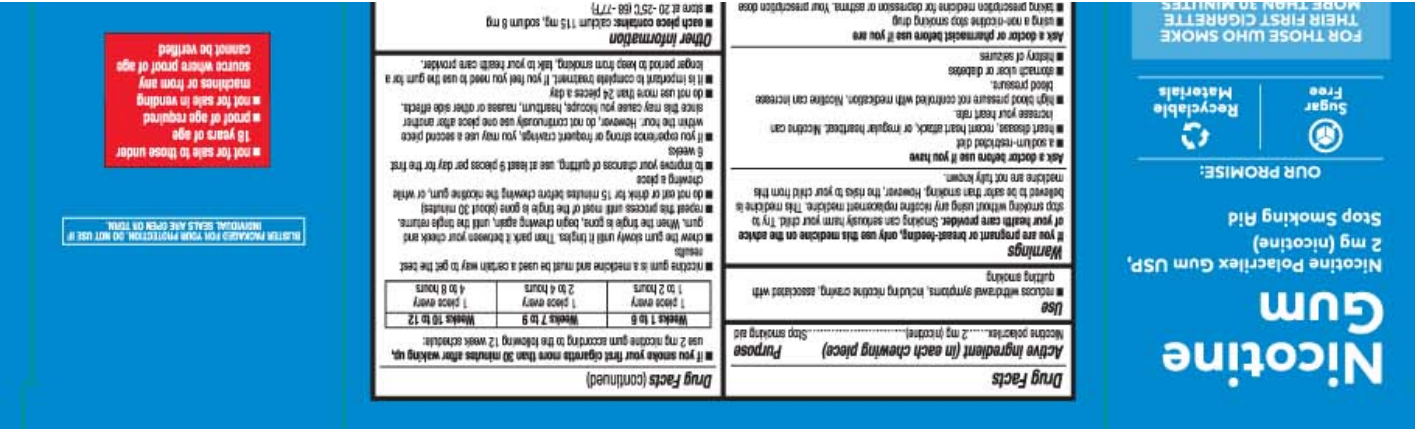
Directions

If you are under 18 years of age, ask a doctor before use.
Before using this product, read the enclosed Leaflet for complete directions and other important information.
Always follow the instructions on your package.
Use this inhaler exactly as directed within 30 minutes of waking up,
and at night as needed.



THEFT SURVEILLANCE TAG AREA

AFTER WAKING UP
If you smoke your first cigarette WITHIN
30 MINUTES of waking up, use Nicotine
Patches gum USP, 4 mg
sugar free coated nicotine gum



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: 5C5403N26O)			
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)			
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	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-3313-9	20 in 1 CARTON	01/31/2020	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11822-3313-6	100 in 1 CARTON	01/31/2020	
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	

Labeler - Rite Aid Corporation (014578892)

Revised: 2/2023

Rite Aid Corporation