

NICOTINE POLACRILEX- nicotine polacrilex gum, chewing
Rising Pharma Holdings, Inc.

Nicotine Polacrilex Gum USP, Coated Mint Flavor 4 mg

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 120 mg, sodium 8 mg
- store at 20 -25°C (68 -77°F)
- protect from light

Inactive Ingredients acacia, acesulfame potassium, carnauba wax, D&C yellow #10 aluminum lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide, xylitol

Questions or comments?

Call **1-844-474-7464**

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Principal Display Panel (4 mg Gum)

Compare to the active ingredient in Nicorette® Gum

Nicotine Gum

Stop Smoking Aid

NICOTINE POLACRILEX GUM USP, 4 MG (NICOTINE)

- **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**
- **Gluten Free**

4 mg

Coated Mint Flavor

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.

To remove the gum, tear off single unit.

Peel off backing starting at corner with loose edge.

Push gum through foil.

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS 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.

Package Label (4 mg Gum)

NDC 57237-323-01
*Compare to the active ingredient in Nicorette® Gum



Nicotine Gum

Stop Smoking Aid

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PLD-A623A F030829



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Drug Facts (continued)

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Other information

- each piece contains: calcium 120 mg, sodium 8 mg
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- protect from light

Inactive ingredients acacia, acetaminophen, croscarmellose, DSC yellow #10 aluminum lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide, xylitol

Questions or comments?
Call 1-844-474-4644

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

Issued: 04/2023
Distributed by:
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East Brunswick, NJ 08816

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No Art-Lot/Exp Print Area

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To remove the gum, tear off single unit.



Peel off backing starting at corner with nose edge.



Push gum through hole.



NDC 57237-323-01

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Nicotine Gum

Stop Smoking Aid

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4 mg



Actual Size
Coated Mint Flavor

100 Pieces, 4 mg each



Nicotine Gum

Stop Smoking Aid

NICOTINE POLACRILEX GUM USP, 4 MG (NICOTINE)

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-323
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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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	yellow	Score	no score
Shape	SQUARE	Size	14mm
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-323-01	10 in 1 CARTON	08/10/2023	
1		10 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	ANDA078697	08/10/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)