NICOTINE POLACRILEX- nicotine polacrilex gum, chewing Dr. Reddy's Laboratories Inc.

Nicotine Polacrilex Gum Coated Ice Mint 4 mg ANDA204833 - Equate

Drug Facts

Active ingredient (in each chewing piece)

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

- 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	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

• 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 Nicorrette® Gum*

FREE | SUGAR

FROM | FREE

Nicotine Gum

Nicotine Polacrilex Gum USP,

2 mg (nicotine)

Stop Smoking Aid

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

If you smoke your first cigarette <u>MORE THAN</u> 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

TO INCREASE YOUR SUCCESS IN QUITTING:

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





NEC XXXXX-XXX-XX "Compare to the active ingredient in Nicorette® Gum

Nicotine Gum

Nicotine polacrilex gum USP, 2 mg (nicotine) Stop Smoking Aid

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

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



110 Pieces, 2 mg EACH

Nicotine Gum

Nicotine polacrilex gum USP, 2 mg (nicotine) Stop Smoking Aid

Lot/Exp Print Area -trA oN

"Th is products snot me nutectored or distrib uts day Helson group chempanius, distributor of N coreses" Gum.

CA KACKA WKACKOKKA & TMESA 2016 Guestions of comments?

Into We ingredients assasses assasses, by they be they

who do have for the form of a minimal before close and men cancer than of a principal control of the form of the f

I tood and leg of your all dross is be used Turnth mean indoor no a line by the bit I have been used to the top of the bit of the b

on a sub-lift should be a paged on may 81 white use may the estigence of a shift shift a seed as the case a shift may are a find a militarchal introduct and to estimate the construction of the case of the white, two me and also make an off shift and policy and and a sound a gain on the man of a shift of the page and a shift on page and the mag whiten page.

your freeze though scient keen of with the scient fired where the scient scient and the scient scien

where so is a pick on this on the solice of the order order order order or order or order order or order order



Myou smakeyo ur Aft é dyneke <u>W MH NI 3</u>0 MNU UT 25 d' wak y up, ur Alic olim Plac Allen Der Ling (Ar ni y

MORE THAN 13 OM INOTES A STER WANTENGE UP SOR THOS EW HOSMOXET HEIR FIRST OGARRETTE

this triboniz q of 2 (sn trooking Ald Moodine polocifiex gum USP, 2 mg

Micotine

Nicotine Polacrilex Gum USP, 2 mg Cinnamon Coated

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75907-299

Route of Administration ORAL

Active Ingredient/Active Moiety

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C897Y6R) (NICOTINE - UNII:6M3C897Y6R)	NICOTINE	2 mg

Inactive Ingredients		
Ingredient Name	Strength	
ACACIA (UNII: 5C5403N26O)		
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
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)		

Product Characteristics				
Color	pink (Light)	Score	no score	
Shape	SQUARE	Size	14mm	
Flavor	CINNAMON	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
-	NDC:75907-299-	00 : 1 CARTON	07/01/2025	

_	80	OU III 1 CARTUN	01/01/2023	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:75907-299- 15	150 in 1 CARTON	07/01/2025	
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	ANDA079216	07/01/2025	

Labeler - Dr. Reddy's Laboratories Inc. (802315887)

Revised: 5/2025 Dr. Reddy's Laboratories Inc.