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 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

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	1 piece	1 piece overy
every	every	1 piece every 4 to 8 hours
1 to 2 hours	2 to 4 hours	4 10 0 110 11 5

- 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

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 Use Enough - Cheu 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.





sta



Compare to the active ingredient of Nicorette® Gum® NDC 11822-2331-2

Nicotine Gum



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

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 USP, 4 mg

sugar free coated nicotine gum



AVOF PIECES 2 mg EACH

ACTUAL SIZE COATED

ma

und sugadu du y

SUODOSUID

paper and throw away in the track. In case of overdose, got medical help or contact a Poison Control Centor (1-600-222-1222) right away.

way have not at mach of children and pets. Proces of not of the precess of gum in the process of the process of the process of the process of gum in

dentities worknoom, and reaction fouch as difficulty braching or wyou have symptome of an allergic reaction (such as difficulty braching or astitution) astitution astitut

Compare to the active ingredient of Nicorette® Gum* NDC 11822-2331-2

Nicotine Jm

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



moo.bisetin.www СӨМЬ НІГГ' БӨ 12011 ВЦЕ ӨІD' 30 НОИLES ГӨИЕ' PISTRIBUTED BY:

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

Cal 1-877-753-3855 Norday-Finday 9AM-5PN EST



ABITA BAT SOMALJEWING THEMT

	Inactive ingredients acrets acteurs acteurs pressure in brydered hydrorychinary, comusia war bryde for a miles hydrorychy hydrorychinary, comusia war articla cimani mous branonia cyclin actionale war articla cimani duok a wha branonia cyclin actionale wardiae fibr than duok a wha	
20 MINULES of majority of the society of a society and an analysis of assession of a signal society of a society of	Other information a set place ondense calcum 115 mg, socium 11 mg a stare 4120-515 (BG -777) a provid them (pph	ceutor pe nauged ceutor puesto quarte
EOK LHOSE MHO SWOKE Root haven an intervention within the second and the second a	aice fine may success a day at the important for some than 24 percent and With important the complete threatment. If your field you meet to use the gum for a broger period to keep from moving, task to your freeth care provider.	fue wout so souponu Buppan in ale jo jood w paynbai ale jo jood w ale jo sirad gi
A hat a doctory before a wind with a more interest of the more a	tan Tara and year and a second a stat stat stat stat stat stat stat s	m not for eale to three under
Microstine Polacitikex Gum USP, Microstinex Gum U	bre sleeto ruor naavted ti zing nerti. seignit ti timu yiwola mug att warb a amiter sland off timu niega pelwerb eined anno si slandt eft perfiki mun	HIGHL TO READ 244 STY25 THIOMOM HELSING 4 350 Ion of Holisiona Wirka No. (2544594 Helsing)
(a). Im patielossee grinero antionin gelacitidane landarge ascutation accutation antioning antio	D reading to the sector of	
A Modine and a model of the second and a model of the second and t	Aip dinkawa wana sebaruha kana kana atawa ukana kata ya kuka kuka kuka kuka kuka kuka kuka	
ey Grug storey Grug	Drug Facts (continued)	

. .

NICOTINE POLACRII	LEX			
nicotine polacrilex gum, chewin	g			
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (So	Item Code (Source) NDC:1	
Route of Administration	ORAL			
Active Ingredient/Active M	loiety			
In	igredient Name		Basis of Stren	ngth Strength
NICOTINE (UNII: 6M3C89ZY6R) (N	ICOTINE - UNII:6M3C89ZY	6 R)	NICOTINE	2 mg
Inactive Ingredients				
Ingredient Name				
ACACIA (UNII: 5C5403N26O)				
ACESULFAME POTASSIUM (UNII:	23OV73Q5G9)			
CARNAUBA WAX (UNII: R12CBM0B	EIZ)			
FD&C RED NO.40 (UNII: WZB9127	'XOA)			
HYDROXYPROPYL CELLULOSE,	UNSPECIFIED (UNII: 9 XZ8	H6 N6 O H)		
BUTYLATED HYDROXYTOLUEN				
SODIUM BICARBONATE (UNII: 8M	/DF5V39QO)			
SODIUM CARBONATE (UNII: 45P3	261C7T)			
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIO XIDE (UNII: 15FIX9)	V2JP)			
XYLITOL (UNII: VCQ006KQ1E)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
HYPROMELLOSE, UNSPECIFIED	(UMI: 3NAW29V3WU)			
Product Characteristics				
Color YELLO	OW.	Score	r	10 score
COLOI IELEC		50010	1	

Shape	SQUARE	Size		14mm
Flavor	CINNAMON	Imprint Code		
Contains				
Packaging				
# Item Code	Package De	Package Description		Marketing End Dat
1 NDC:11822-2331-2	100 in 1 CARTON		01/31/2020	
	100 in 1 CARTON 1 in 1 BLISTER PACK; Type 0:	Not a Combination Product		
		Not a Combination Product		
		Not a Combination Product		
1	1 in 1 BLISTER PACK; Type 0:	Not a Combination Product		
1 Marketing In	1 in 1 BLISTER PACK; Type 0: formation			Markating End Date
1 NDC:11822-2331-2 1 Marketing In Marketing Catego ANDA	1 in 1 BLISTER PACK; Type 0: formation			Marketing End Date

Labeler - Rite Aid Corporation (014578892)

Revised: 4/2020

Rite Aid Corporation