## NICOTINE POLACRILEX COATED MINT- nicotine polacrilex gum, chewing CVS Pharmacy

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Nicotine Polarilex Coated Mint 2 mg and 4 mg - CVS

#### Drug Facts

#### Active ingredient (in each chewing piece) - 2 mg

Nicotine polacrilex 2 mg (nicotine)

#### Active ingredient (in each chewing piece) - 4 mg

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 - 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	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.

#### Directions - 4 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 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	1 piece
every	every	every
1 to 2	2 to 4	4 to 8
hours	hours	hours

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- 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

#### Other information - 4 mg

- each piece contains: calcium 120 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.

#### Inactive ingredients - 4 mg

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 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 in Nicorette® Gum\*

Sugar Free

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.

#### 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.

Use with a support program as directed in the enclosed User's Guide.

- 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

# BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE OPEN OR TORN.

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

#### Distributed by:

CVS Pharmacy, Inc.

One CVS Drive Woonsocket, RI 02895

### Package label 2 mg



CVS HEALTH Sugar Free Nicotine Gum Coated Mint Flavor

#### Principal display panel 4 mg

Compare to the active ingredient in Nicorette® Gum\*

Sugar Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 4 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 MORE THAN 30 MINUTES of waking up, use Nicotine Polacrilex Gum USP, 2 mg.

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CVS Pharmacy, Inc.

One CVS Drive Woonsocket, RI 02895

Package label 4 mg

### 🔍 minute clinic' START TO STOP CAN HELP YOU QUIT

CVS.com/StartToStop

Visit MinuteClinic® for personal counseling with a licensed provider.

Drug Facts (continued)

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, acesulfa me notassium. 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

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THEFT SURVEILLANCE TAG AREA

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PLD-D623A FC008082



**Coated Mint Flavor** 10 PIECES, 4 mg EACH

#972925



**CVS HEALTH Nicotine Gum Coated Mint Flavor** 

as directed

with a s

Use

You

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#### NICOTINE POLACRILEX COATED MINT nicotine polacrilex gum, chewing **Product Information** HUMAN OTC DRUG NDC:69842-428 **Product Type** Item Code (Source) BUCCAL **Route of Administration**

#### **Drug Facts**

	n each chewing piece) (nicotine)	
<b>Use</b> ■ reduces withdraw quitting smoking	al symptoms, including nicotine	craving, associated wit
your health care provider. smoking without using any i	ast-feeding, only use this med Smoking can seriously harm yo nicotine replacement medicine. owever, the risks to your child fr	ur child. Try to stop This medicine is believe
heartbeat. Nicotine can incr	heart disease, recent heart a ease your heart rate. I high b Nicotine can increase blood pres	lood pressure not
	st before use if you are smoking drug taking presc prescription dose may need to b	
you get symptoms of nico diarrhea, weakness, and rap	ems occur 🔳 irregular heartbe tine overdose such as nausea, v	omiting, dizziness,
	ren and pets. Pieces of nicotine	
	nd pets sick. Wrap used pieces o case of overdose, get medical he 1222) right away.	
throw away in the trash. In of Control Center (1-800-222- Directions if you are under 18 year before using this product, and other important informa if you smoke your first of 2 ng nicotine gum if yo	case of overdose, get medical he	Ip or contact a Poison ise for complete directions n your quit day s after waking up, use within 30 minutes of
throw away in the trash. In d Control Center (1-800-222- Directions III you are under 18 years III you are under 18 years III you smoke your first u III you smoke your first u III you smoke your first u waking up, use 4 mg nicoti Weeks 1 to 6	zase of overdose, get medical he (222) right away. s of age, ask a doctor before u read the enclosed User's Guide tion ■ begin using the gum o igarette more than 30 minute ou smoke your first eigarette ne gum according to the followi Weeks 7 to 9	Ip or contact a Poison ise for complete directions n your quit day s after waking up, use within 30 minutes of ng 12 week schedule: Weeks 10 to 12
throw away in the trash. In Control Center (1-800-222- Directions If you are under 18 year before using this product, and other important informa If you smoke your first of 2 mg nicotine gum III y waking up, use 4 mg nicoti	case of overdose, get médical he 1222) right away. s of age, ask a doctor before i read the enclosed User's Guide tion m begin using the gum o sigarette more than 30 minute ou smoke your first eigarette ne gum according to the followi	Ip or contact a Poison ise for complete directions n your quit day s after waking up, us within 30 minutes of ng 12 week schedule:

	······	ient/Act	ive Moiety				
		Ing	gredient Name	e	Basis of Str	rength	Strength
NI	IICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)				NICOTINE		2 mg
lr	active Ingre	dients					
	9		Inared	lient Name			Strength
AC	CACIA (UNII: 5C54	03N26O)	<b>J</b>				
AC	ESULFAME POT	ASSIUM (	UNII: 230V73Q5G	9)			
C/		UNII: R12C	BMOEIZ)				
H)	DROXYPROPYL	CELLULO	SE, UNSPECIFIE	<b>D</b> (UNII: 9XZ 8H6N6OH)			
M	AGNESIUM OXID	<b>E</b> (UNII: 34	A3U0GI71G)				
sc	DIUM BICARBO	NATE (UN	II: 8MDF5V39QO)				
sc	DIUM CARBON	ATE (UNII:	45P3261C7T)				
TÆ	LC (UNII: 7SEV7J	4R1U)					
XY	<b>LITOL</b> (UNII: VCC	006KQ1E)					
P	roduct Chara	acterist	ics				
Сс	olor		white	Score		no score	9
Sł	nape		SQUARE	Size		14mm	
Fl	avor		MINT	Imprint Code			
Сс	ontains						
Pa	ackaging						
	ackaging Item Code		Package De	scription	Marketing Start Date	Mar	keting End Date
		10 in 1 C/	-	scription	-	Mar	
#	Item Code NDC:69842-428-		ARTON	scription 0: Not a Combination	Date	Mar	_
# 1	Item Code NDC:69842-428-	1 in 1 BLI Product 120 in 1 (	ARTON STER PACK; Type CARTON	0: Not a Combination	Date	Mar	
# 1 1	Item Code NDC:69842-428- 79 NDC:69842-428- 22	1 in 1 BLI Product 120 in 1 (	ARTON STER PACK; Type CARTON		<b>Date</b> 01/01/2014	Mar	
# 1 1 2	Item Code NDC:69842-428- 79 NDC:69842-428-	1 in 1 BLI Product 120 in 1 C 1 in 1 BLI Product 160 in 1 C	ARTON STER PACK; Type CARTON STER PACK; Type CARTON	0: Not a Combination 0: Not a Combination	<b>Date</b> 01/01/2014	Mar	_
# 1 2 2	Item Code NDC:69842-428- 79 NDC:69842-428- 22 NDC:69842-428-	1 in 1 BLI Product 120 in 1 C 1 in 1 BLI Product 160 in 1 C	ARTON STER PACK; Type CARTON STER PACK; Type CARTON	0: Not a Combination	Date 01/01/2014 01/01/2014	Mar	_
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## NICOTINE POLACRILEX COATED MINT

<b>Product Infor</b>	mation							
Product Type		HUMAN OTC DRU	JG	ltem Code	(Source)	NDC:6	59842-430	
Route of Admini	istration	BUCCAL						
Active Ingred	ient/Active	Moiety						
		dient Name			Basis of St	rength	Strength	
NICOTINE (UNII: 6N	-		3C89ZY6R)		NICOTINE		4 mg	
Inactive Ingre	dients							
		Ingredien	t Name				Strength	
ACACIA (UNII: 5C54								
ACESULFAME POT		· ·						
D&C YELLOW NO.				CNCOLI)				
			NII: 9XZ8H0	6N6OH)				
MAGNESIUM OXID								
	SODIUM CARBONATE (UNII: 45P3261C7T)							
TALC (UNII: 7SEV7J4R1U)   TITANIUM DIOXIDE (UNII: 15FIX9V2JP)								
		V2IP)						
	e (UNII: 15FIX9)	V2JP)						
TITANIUM DIOXID	e (UNII: 15FIX9)	V2JP)						
TITANIUM DIOXID XYLITOL (UNII: VCC	E (UNII: 15FIX9) 0006KQ1E)	V2JP)						
TITANIUM DIOXID XYLITOL (UNII: VCC Product Chara	E (UNII: 15FIX9 2006KQ1E) Acteristics							
TITANIUM DIOXID XYLITOL (UNII: VCC Product Chara Color	E (UNII: 15FIX9 2006KQ1E) Acteristics yell	ow	Score			no scor	e	
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TITANIUM DIOXID XYLITOL (UNII: VCC Product Chara Color Shape	e (UNII: 15FIX9) 2006KQ1E) acteristics yello SQU	ow JARE	Size	Code			e	
TITANIUM DIOXID XYLITOL (UNII: VCC Product Chara Color Shape Flavor Contains Packaging	E (UNII: 15FIX9) 2006KQ1E) Acteristics yella SQU MIN	ow JARE	Size Imprint		arketing Starl Date	14mm	e keting End Date	
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FITANIUM DIOXID   XYLITOL (UNII: VCC   Product Chara   Color   Shape   Flavor   Contains   Packaging   # Item Code   1 NDC:69842-430-79	E (UNII: 15FIX9) 2006KQ1E) Acteristics yello SQU MIN Pa 10 in 1 CARTC	ow JARE T Ackage Descrij	Size Imprint	M. 01/0	Date	14mm	keting End	
TITANIUM DIOXID XYLITOL (UNII: VCC Product Chara Color Shape Flavor Contains Packaging # Item Code 1 NDC:69842-430- 79 1	E (UNII: 15FIX9) OOGKQ1E) ACTERISTICS Yello SQU MIN Pa 10 in 1 CARTO 1 in 1 BLISTEF	ow JARE T Ackage Descrip	Size Imprint	01/0 nation	Date	14mm	keting End	
ritanium dioxid xyLitol (UNII: VCC Product Chara Color Shape Flavor Contains Packaging # Item Code 1 NDC:69842-430- 79 1 NDC:69842-430- 2 NDC:69842-430- 2	E (UNII: 15FIX9) 2006KQ1E) ACTERISTICS yella SQU MIN N 10 in 1 CARTC 1 in 1 BLISTEF Product 120 in 1 CART	ow JARE T Ackage Descrip	Size Imprint ption	Ma 01/0 nation 01/0	<b>Date</b> 1/2014	14mm	keting End	
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Marketing Information						
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
ANDA078697	01/01/2014					
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date				

## Labeler - CVS Pharmacy (062312574)

Revised: 2/2022

**CVS** Pharmacy