NICORETTE WHITE MINT NICOTINE POLACRILEX- nicotine gum, chewing Lil' Drug Store Products, Inc.

Nicorette [®] White Mint nicotine polacrilex gum, chewing

Drug Facts

Active ingredient (in each chewing piece)

Nicotine polacrilex (equal to 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 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	1 piece every 2	1 piece every 4
to 2 hours	to 4 hours	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 94 mg, sodium 13 mg
- store at 20 25°C (68 77°F)
- protect from light

Inactive ingredients

acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

Questions or comments?

call toll-free **1-800-419-4766**

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PRINCIPAL DISPLAY PANEL - 10 Piece Blister Pack Carton

This package size may not be a full day's supply; it is intended to start or continue a quit attempt.

NDC 0135-0475-17

gsk

Nicorette [®] nicotine polacrilex gum, 4 mg • stop smoking aid Gum

4

mg

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 Nicorette [®] 2 mg Gum

Coated FOR BOLD FLAVOR

White Ice Mint ®

10 PIECES, 4 mg EACH



F5271-CV-A

NICORETTE WHITE MINT NICOTINE POLACRILEX

nicotine gum, chewing

Product Informa	tion						
Product Type		HUMAN OTC DRU	JG It	em Code	(Source)	NDC:29	485-5271
Route of Administra	tion	ORAL					
Active Ingredient	Active	Moiety					
	Ingred	ient Name			Basis of Stre	ength	Strength
NICOTINE (UNII: 6M3C8	9ZY6R) (NIC	COTINE - UNII:6M3	3C89ZY6R)		NICOTINE		4 mg
Inactive Ingredie	nts						
	70511176)	Ingredient	Name				Strength
POLACRILIN (UNII: RCZ							
ACESULFAME POTASS CARNAUBA WAX (UNII:							
HYPROMELLOSE, UNSI		-	VO)				
MAGNESIUM OXIDE (UI			,				
MENTHOL, UNSPECIFI			\)				
PEPPERMINT OIL (UNII:							
POLYSORBATE 80 (UNI	I: 60ZP39Z	(G8H)					
SODIUM BICARBONAT	E (UNII: 8MI	DF5V39QO)					
SODIUM CARBONATE (UNII: 45P32	261C7T)					
SUCRALOSE (UNII: 96K6	5UQ3ZD4)						
TITANIUM DIOXIDE (UN	III: 15FIX9V2	2JP)					
XYLITOL (UNII: VCQ006	(Q1E)						
Product Characte	eristics						
Color	white		Score	Score		no score	
Shape	SQUA	ARE	Size			15mm	
Flavor	MINT		Imprint C	ode		N4	
Contains							
Packaging							
# Item Code	Pa	ckage Descri	ntion	Ma	arketing Start	Mar	ceting End

1 NDC:29485- 5271-1	1 in 1 CARTON	06/29/2009				
1	10 in 1 BLISTER PACK; Type 0: Not a Combination Product					
Marketing Information						
Marketing	Information					
Marketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
Marketing	Application Number or Monograph	-	-			

Labeler - Lil' Drug Store Products, Inc. (093103646)

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Lil' Drug Store Products, Inc.