# NICORETTE FRUIT CHILL NICOTINE POLACRILEX- nicotine gum, chewing Lil' Drug Store Products, Inc.

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## Nicorette <sup>®</sup> Fruit Chill <sup>®</sup> 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

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80,

### **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.

gsk

NDC 0135-0242-11

Nicorette <sup>®</sup> 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 MORE THAN 30 MINUTES after waking up, use Nicorette <sup>®</sup> 2 mg Gum

Coated FOR BOLD FLAVOR

Fruit Chill ®

10 PIECES, 4 mg EACH



#### **Drug Facts** (continued)

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#### KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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Active ingredient (in each chewing piece)

Purpose

1. You must be

six weeks.

User's Guide.

and for a FREE

Nicotine polacrilex (equal to 4 mg nicotine).

Stop smoking aid

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#### Warnings

not for sale to those under

18 years of age

proof of age required

not for sale in vending machin

or from any source wher

proof of age

This product is

use if individual

broken, open, or

Trademarks are owned by or licensed to the GSK group of companies.

backings are

blisters or printed

protected in sealed blisters. Do not

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#### LIFT PANEL FOR CONTINUED DRUG FACTS

#### Drug Facts (continued)

#### Stop use and ask a doctor if

- mouth, teeth or jaw problems occur
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  \*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

### NICORETTE FRUIT CHILL NICOTINE POLACRILEX

nicotine gum, chewing

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:29485-5270

Route of Administration ORAL

### **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)

NICOTINE

NICOTINE

4 mg

### **Inactive Ingredients Ingredient Name** Strength POLACRILIN (UNII: RCZ785HI7S) ACESULFAME POTASSIUM (UNII: 230V73Q5G9) CARNAUBA WAX (UNII: R12CBM0EIZ) D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) **ALUMINUM OXIDE** (UNII: LMI26O6933) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) MAGNESIUM OXIDE (UNII: 3A3U0GI71G) MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) PEPPERMINT OIL (UNII: AV092KU4JH) POLYSORBATE 80 (UNII: 60ZP39ZG8H) **SODIUM CARBONATE** (UNII: 45P3261C7T) **SUCRALOSE** (UNII: 96K6UQ3ZD4) **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) XYLITOL (UNII: VCQ006KQ1E) **ACACIA** (UNII: 5C5403N260)

Product Characteristics			
Color	yellow	Score	no score
Shape	SQUARE	Size	15mm
Flavor	FRUIT	Imprint Code	N4
Contains			

### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485- 5270-1	1 in 1 CARTON	09/14/2009	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing I	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA020066	09/14/2009		

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

Revised: 7/2023 Lil' Drug Store Products, Inc.