

NICOTAC NICOTINE POLACRILEX COATED FRUIT- nicotine gum, chewing
Lil' Drug Store Products, Inc.

Nicotac™ Nicotine Polacrilex Gum, 2mg
Coated Fruit

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, a recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your 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 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 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 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 hiccups, heartburn, nausea, or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you still feel the 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 8 mg
- store at 20–25°C (68–77°F)
- protect from light

Inactive ingredients

acacia, acesulfame potassium, carnauba wax, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium oxide, xylitol

Questions or comments?

call 1-877-440-7867

Distributed by: Lil' Drug Store Products, Inc., 9300 Earhart Lane SW
Cedar Rapids, IA 52404

PRINCIPAL DISPLAY PANEL - 2 mg Gum Blister Pack Carton

NICOTAC™

NICOTINE POLACRILEX GUM USP

2

mg

(nicotine)

STOP SMOKING AID

Coated

Fruit Gum

FOR THOSE WHO SMOKE THEIR
FIRST CIGARETTE MORE THAN
30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette
WITHIN 30 MINUTES of waking
up, use Nicotine Polacrilex
Gum USP, 4 mg

Compare to the active ingredient in
Nicorette® Fruit Chill™ Coated Gum*

10 Pieces

Sugar Free, 2 mg Each

NICOTAC™
NICOTINE POLACRILEX GUM USP

2 mg
(nicotine)

NICOTAC™
NICOTINE POLACRILEX GUM USP

2 mg
(nicotine)

STOP SMOKING AID

Coated

Fruit Gum



FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicotine Polacrilex Gum USP, 4 mg

Compare to the active ingredient in Nicorette® Fruit Chill™ Coated Gum*

10 Pieces
Sugar Free, 2 mg Each



Fruit
10 Pieces

NICOTAC™
NICOTINE POLACRILEX GUM USP
STOP SMOKING AID
2 mg
(nicotine)

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

Drug Facts

Active ingredient Purpose (in each chewing piece)
Nicotine polacrilex
2 mg (nicotine)..... 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, a recent heart attack, or irregular heartbeat. Nicotine can

Drug Facts (continued)

increase your heart rate.
high blood pressure not controlled with medication. Nicotine can increase your 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)

LIFT PANEL FOR CONTINUED DRUG FACTS

EXP
LOT



Drug Facts (continued)

do not use more than 24 pieces a day
it is important to complete treatment. If you still feel the 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 8 mg
store at 20–25°C (68–77°F) protect from light

Inactive ingredients

acacia, acesulfame potassium, carnauba wax, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium oxide, xylitol

Questions or comments? call 1-877-440-7867

Free Audio CD Upon Request. See Inside.



1) To remove the gum, tear off single unit.



2) Peel off backing starting at corner with loose edge.

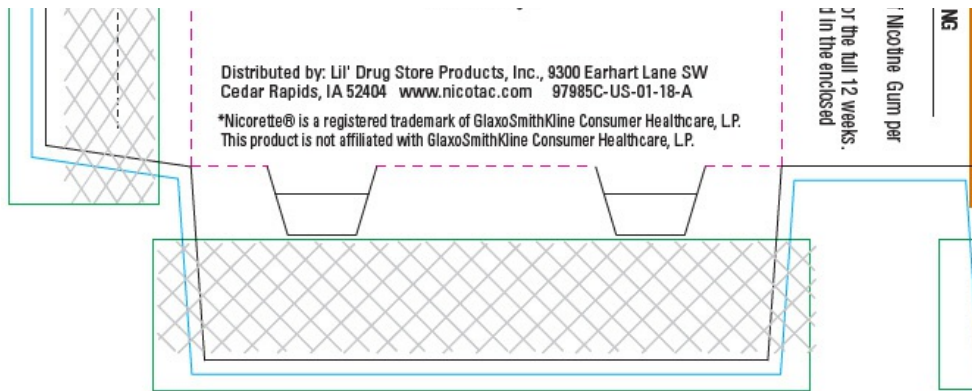


3) Push gum through foil.

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.

TO INCREASE YOUR SUCCESS IN QUITTING

1. You must be motivated to quit.
2. Use Enough: Chew at least 9 pieces of gum during the first 6 weeks.
3. Use Long Enough: Use Nicotine Gum for at least 12 weeks.
4. Use with a Support Program as directed in the Nicotine Gum User's Guide.



Drug Facts (continued)

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 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 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 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 hiccups, heartburn, nausea, or other side effects. ▶

NICOTAC NICOTINE POLACRILEX COATED FRUIT

nicotine gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9805
Route of Administration	BUCCAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Nicotine (UNII: 6M3C89ZY6R) (Nicotine - UNII:6M3C89ZY6R)	Nicotine	2 mg

Inactive Ingredients

Ingredient Name	Strength
Acacia (UNII: 5C5403N26O)	
Acesulfame Potassium (UNII: 23OV73Q5G9)	

Carnauba Wax (UNII: R12CBM0EIZ)
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)
Magnesium Oxide (UNII: 3A3U0GI71G)
Sodium Bicarbonate (UNII: 8MDF5V39QO)
Sodium Carbonate (UNII: 45P3261C7T)
Sucralose (UNII: 96K6UQ3ZD4)
Talc (UNII: 7SEV7J4R1U)
Titanium Dioxide (UNII: 15FIX9V2JP)
Xylitol (UNII: VCQ006KQ1E)

Product Characteristics			
Color	YELLOW (Light Yellow)	Score	no score
Shape	SQUARE	Size	14mm
Flavor	FRUIT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-9805-5	10 in 1 CARTON	10/15/2018	
1		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	ANDA079044	04/03/2018	

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