

**NICOTINE POLACRILEX COATED FRUIT- nicotine polacrilex gum, chewing**  
**Publix Supermarkets, Inc.**

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**Nicotine Polacrilex Gum 2 mg and 4 mg Coated Fruit - Publix**

***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:

<b>Weeks 1 to 6</b>	<b>Weeks 7 to 9</b>	<b>Weeks 10 to 12</b>
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 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:

<b>Weeks 1 to 6</b>	<b>Weeks 7 to 9</b>	<b>Weeks 10 to 12</b>
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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

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- store at 20 - 25°C (68 - 77°F)
- protect from light

#### ***Inactive ingredients - 2 mg***

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 dioxide and xylitol.

#### ***Inactive ingredients - 4 mg***

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 lake, 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 dioxide and xylitol.

## **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

COATED FRUIT FLAVOR

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, 4 mg

2 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 for the full 12 weeks.
4. **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 protect. Do not use if individual seals are open or torn.

\*This product is not manufactured or distributed by Haleon group of companies, distributor of Nicorette® Gum.

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.,

3300 PUBLIX CORPORATE PARKWAY,

LAKELAND, FL 33811, 1-888-267-3037

**Package label 2 mg**



SUGAR FREE

# nicotinegum

NICOTINE POLACRILEX GUM

USP, 2 mg (nicotine)

STOP SMOKING AID



NDC 50062-503-44

SUGAR FREE

# nicotinegum

NICOTINE POLACRILEX GUM

USP, 2 mg (nicotine)

STOP SMOKING AID

COATED  
FRUIT FLAVOR

- **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**



**2mg** 100 PIECES OF GUM  
2 mg EACH

ACTUAL SIZE  
\*Compare to the active ingredient in Nicorette® Gum

### TO INCREASE YOUR SUCCESS IN QUITTING:

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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.



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.

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public.com

PRODUCT OF BELGIUM

"The product is not manufactured or distributed by Helmar Group of companies; distributor of Nicorette® gum."

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to cause dizziness and drowsiness. Keep out of reach of children and pets. Nicotine gum pieces of gum in plastic, aluminum, or other packaging may contain small amounts of lead.

Stop use and ask a doctor if you have symptoms of nicotine overdose such as nausea, vomiting, dizziness, drowsiness, weakness, and rapid heartbeat.

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to cause dizziness and drowsiness. Keep out of reach of children and pets. Nicotine gum pieces of gum in plastic, aluminum, or other packaging may contain small amounts of lead.

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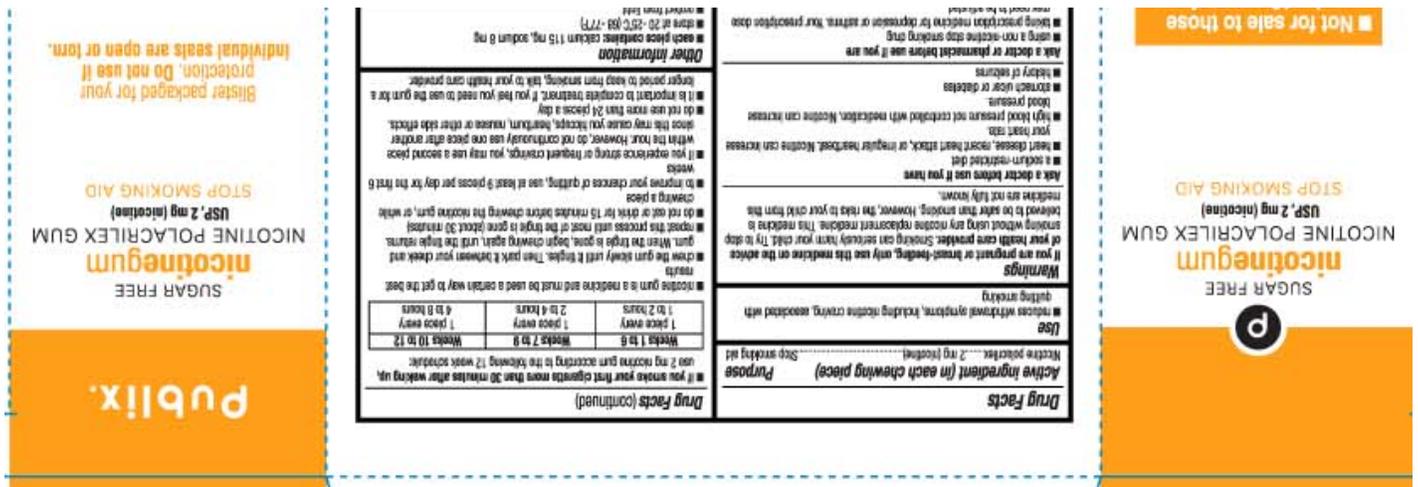
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**PUBLIX Sugar Free Nicotine Coated Fruit Flavor**

**Principal display panel 4 mg**

\*Compare to the active ingredient in Nicorette® Gum

SUGAR FREE

nicotinegum

NICOTINE POLACRILEX GUM USP, 4 mg (nicotine)

STOP SMOKING AID

COATED FRUIT FLAVOR

FOR THOSE SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette MORE THAN 30 MINUTES after waking up use Nicotine Polacrilex Gum USP, 2 mg

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.
4. **Use with a Support Program** as directed in the enclosed User's Guide.
  - Not for sale to those under 18 years of age.
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  - 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.

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LAKELAND, FL 33811, 1-888-267-3037

**Package label 4 mg**



SUGAR FREE

# nicotinegum

NICOTINE POLACRILEX GUM

USP, 4 mg (nicotine)

STOP SMOKING AID



NOC 56062-S04-44

SUGAR FREE

# nicotinegum

NICOTINE POLACRILEX GUM

USP, 4 mg (nicotine)

STOP SMOKING AID

COATED  
FRUIT FLAVOR

- **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 Nicotine Polacrilex Gum USP, 2 mg**



ACTUAL SIZE

**4 mg** 100 PIECES OF GUM  
4 mg EACH

\*Compare to the active ingredient in Nicorette® Gum

### 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.
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.

PUBLIC GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

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PRODUCT OF IRELAND

\*This product is not manufactured or distributed by the parent group of companies, distributor of Nicorette® Gum.

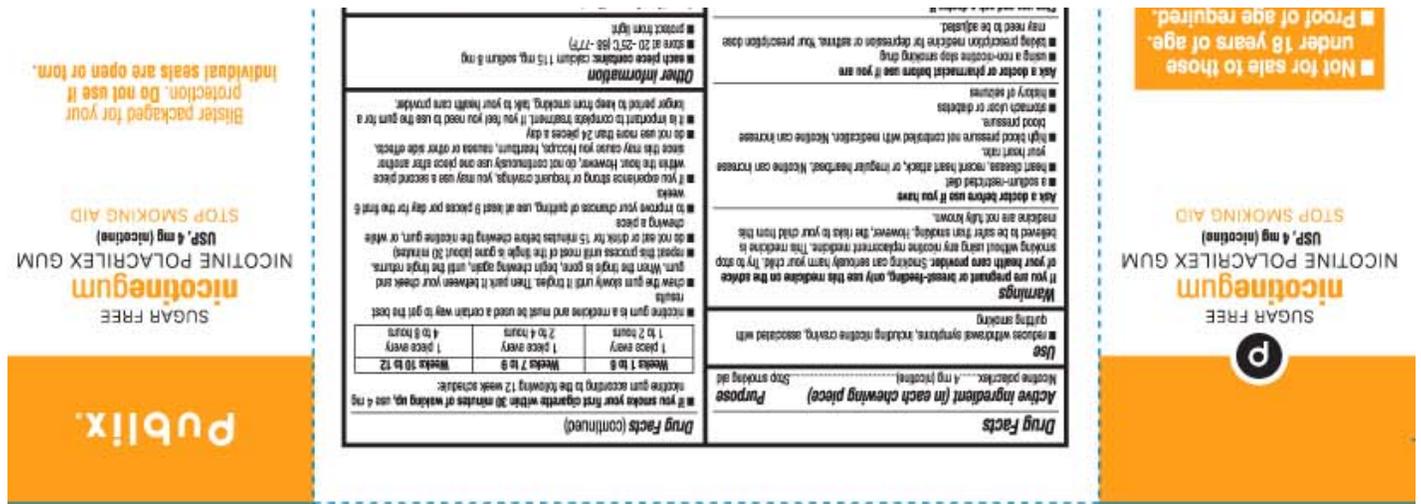
**inactive ingredients** acacia, acetylsalicylic potassium, carboxylated polyacrylamide, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol, sodium lauryl sulfate, sodium polyacrylate, sucralose, tart, titanium dioxide, xylitol

**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.  
Keep out of reach of children and pets. When used pieces of gum may be enough to cause choking or airway obstruction.  
If you have symptoms of an allergic reaction (such as difficulty breathing or rash), dizziness, weakness, and rapid heartbeat, stop use and seek medical attention.  
If you get symptoms of nicotine overdose (such as nausea, vomiting, diarrhea, mouth, teeth, or jaw problems occur), stop use and seek a doctor.



PLD-08218 FC009214

Not for sale in vending machines or from any source where proof of age cannot be verified.



**PUBLIX nicotine Polacrilex Coated Fruit Flavor**

**NICOTINE POLACRILEX COATED FRUIT**

nicotine polacrilex gum, chewing

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-503
<b>Route of Administration</b>	BUCCAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0G171G)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

**Product Characteristics**

<b>Color</b>	brown (light brown)	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>	FRUIT (coated fruit)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-503-44	10 in 1 CARTON	01/01/2014	01/01/2027
1		10 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	01/01/2014	01/01/2027

## NICOTINE POLACRILEX COATED FRUIT

nicotine polacrilex gum, chewing

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-504
<b>Route of Administration</b>	BUCCAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

### Product Characteristics

<b>Color</b>	brown (light tan)	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>	FRUIT (coated fruit)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-504-44	10 in 1 CARTON	01/01/2014	01/01/2027
1		10 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	ANDA079038	01/01/2014	01/01/2027

**Labeler** - Publix Supermarkets, Inc. (006922009)