

**NICOTINE POLACRILEX COATED FRUIT- nicotine polacrilex gum, chewing  
Cardinal Health (Leader) 70000**

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**Nicotine Polacrilex Coated Fruit 2 mg and 4 mg - Leader**

***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>
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.

**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 115 mg, sodium 8 mg
- 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, 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, xylitol.

**Question or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

**Principal display panel 2 mg**

COMPARE TO NICORETTE® FRUIT CHILL® GUM active ingredient

Sugar-Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (nicotine)

Stop Smoking Aid

2 mg

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

**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
  - proof of age required
  - not for sale in vending machines or from any source where proof of age cannot be verified

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

**BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL**

**SEALS ARE OPEN OR TORN.**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

**Package label 2 mg**

**TO INCREASE YOUR SUCCESS IN QUITTING:**

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**Drug Facts (continued)**

**Other information**

- each piece contains: calcium 115 mg, sodium 8 mg
- store at 20-25°C (68-77°F)
- protect from light

**Inactive ingredients**

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**Questions or comments?**  
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Monday-Friday 9AM-5PM EST



NDC 70000-0346-1

**Sugar-Free**

# Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (Nicotine) | Stop Smoking Aid

**2 mg**

**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

**20 PIECES, 2 mg EACH**

CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-5353  
**Essential to Care™ Since 1979**  
Product of Ireland

**Drug Facts**

Active ingredient (in each chewing piece)	Purpose
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, 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**

- 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 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.

ALL LEADER Brand Products have A 100% Money Back Guarantee. Return to place of purchase if not satisfied.

■ 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



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

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

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PLD-E615A  
FC008077

CIN 5420906 REV. 6/22



**LEADER Sugar Free Nicotine Gum Fruit Flavor**

## **Principal display panel 4 mg**

COMPARE TO NICORETTE® FRUIT CHILL® GUM active ingredient\*

Sugar-Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

Stop Smoking Aid

4 mg 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

### **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.
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DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com)

**Package label 4 mg**

**TO INCREASE YOUR SUCCESS IN QUITTING:**

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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.

**Drug Facts (continued)**

**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, 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, xylitol

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PLD-EB21A  
FC008111

**LEADER™**

NDC 70000-0342-1

**Sugar-Free  
Nicotine  
Gum**

Nicotine Polacrilex Gum USP, 4 mg  
(Nicotine) | Stop Smoking Aid

**4 mg**

**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

**COMPARE TO  
NICORETTE®  
COATED FRUIT  
CHILL® GUM  
active ingredient\***

**100% Money  
Back Guarantee**

**20 PIECES, 4 mg EACH**

CIN 5420799 REV. 6/22



**CardinalHealth™**  
DISTRIBUTED BY CARDINAL HEALTH  
DURHAM, OHIO 43007  
www.leader.com 1-800-200-6375  
**Essential to Care™ since 1979**  
Product of Ireland

All LEADER brand Products have a **100% Money Back Guarantee**  
Return to place of purchase if not satisfied.

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Push gum through foil.



Peel off backing starting at corner with base edge.



To remove the gum, tear off single unit.

**Drug Facts**

**Active ingredient (in each chewing piece)** Purpose  
Nicotine polacrilex.....4 mg (nicotine)..... Stop smoking aid

**Use** ■ reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

**Warnings**

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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
- 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.

**LEADER Sugar Free Nicotine Gum 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:70000-0346
<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: 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 brown)	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0346-1	20 in 1 CARTON	07/03/2018	
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	07/03/2018	

## NICOTINE POLACRILEX COATED FRUIT

nicotine polacrilex gum, chewing

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0342
<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>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)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	

**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	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0342-1	20 in 1 CARTON	07/03/2018	
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	ANDA079038	07/03/2018	

Revised: 6/2022

Cardinal Health (Leader) 70000