

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

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**Nicotine Polarilex Coated Mint 2 mg and 4 mg - Leader**

***Drug Facts***

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

Nicotine polacrilex (equal to 2 mg nicotine)

***Active ingredient (in each chewing piece) - 4 mg***

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 (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 120 mg, sodium 8 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

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

acacia, acesulfame potassium, carnauba wax, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide, xylitol.

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

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 aluminum lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide, xylitol.

### **Questions or comments?**

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

### **Principal display panel 2 mg**

COMPARE TO NICORETTE® COATED MINT GUM active ingredient\*

Sugar-Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

Stop Smoking Aid

Coated Mint 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 Haleon group of companies distributor of Nicorette® Mint Gum

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

**SEALS ARE OPEN OR TORN.**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 46017

www.myleader.com

**Package label 2 mg**

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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**

acacia, acesulfame potassium, carnauba wax, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide, xylitol

**Questions or comments?**

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Monday-Friday 9AM-5PM EST

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**LEADER**

NDC 70000-0347-1

**Sugar-Free**

**Nicotine Gum**

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

**2 mg**

**Coated Mint 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

**10 PIECES, 2 mg EACH**



Actual Size

**COMPARE TO NICORETTE® COATED MINT GUM active ingredient\***

**100% Money Back Guarantee**

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Return to place of purchase if not satisfied.

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



Push gum through foil.



Peel off backing starting at corner with loose edge.



To remove the gum, tear off single unit.

**Drug Facts**

**Active ingredient (in each chewing piece)** Nicotine polacrilex (equal to 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, 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.

CIN 5420880 REV. 09/24



PLD-F617B FC009208

**LEADER Sugar Free Nicotine Gum Coated Mint Flavor**

## **Principal display panel 4 mg**

COMPARE TO NICORETTE® COATED MINT GUM active ingredient\*

Sugar-Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

Stop Smoking Aid

4 mg

Coated Mint 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 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 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 Haleon group of companies distributor of Nicorette® Gum

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

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DUBLIN, OHIO 43017

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

**Package label 4 mg**

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**Drug Facts (continued)**

**Other information**

- each piece contains: calcium 120 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 aluminum lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide, xylitol

**Questions or comments?**

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**LEADER™**

NDC 70000-0343-1

**Sugar-Free  
Nicotine  
Gum**

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

**4 mg**

**Coated Mint  
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  
MINT GUM  
active ingredient\***

**100% Money  
Back Guarantee**

**10 PIECES, 4 mg EACH**

CIN 5420922 REV. 09/24



0 96295 13379 0  
PLD-F623B F0009230

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**100% Money Back Guarantee**  
Return to place of purchase if not satisfied.

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Peel off backing starting at corner with loose edge.



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■ you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat  
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**Directions**  
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■ 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:

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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.

**NICOTINE POLACRILEX COATED MINT**

nicotine polacrilex gum, chewing

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0347
<b>Route of Administration</b>	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)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

**Product Characteristics**

Color	white	Score	no score
Shape	SQUARE	Size	14mm
Flavor	MINT	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0347-1	10 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	ANDA078699	07/03/2018	

**NICOTINE POLACRILEX COATED MINT**

nicotine polacrilex gum, chewing

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0343
Route of Administration	BUCCAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

**Inactive Ingredients**

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

**Product Characteristics**

Color	yellow	Score	no score
Shape	SQUARE	Size	14mm
Flavor	MINT	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0343-1	10 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	ANDA078697	07/03/2018	

**Labeler** - Cardinal Health (Leader) 70000 (063997360)