

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

Nicotine Polacrilex Original 2 mg and 4 mg - Leader

Drug Facts

Active ingredient (in each chewing piece) - 2 mg

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:

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.

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:

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.

Other information - 2 mg

- **each piece contains:** calcium 115 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Other information - 4 mg

- **each piece contains:** calcium 110 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients - 2 mg

acesulfame potassium, butylated hydroxytoluene, carnauba wax, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc.

Inactive ingredients - 4 mg

acesulfame potassium, butylated hydroxytoluene, carnauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol and talc.

Questions or comments?

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

Principal display panel 2 mg

COMPARE TO NICORETTE® ORIGINAL GUM active ingredient*

Sugar-Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg Nicotine

Stop Smoking Aid

2 mg

Original Flavor

For Those Who Smoke Their First Cigarette **More Than 30 Minutes** After Waking Up

If You Smoke Their 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 machine 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® Original Gum.

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

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

Package label 2 mg

Drug Facts (continued)

■ 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.

Other information

- each piece contains: calcium 115 mg, sodium 11 mg
- store at 20 -25°C (68 -77°F)
- protect from light

Inactive ingredients acesulfame potassium, butylated hydroxytoluene, carnauba wax, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc

Questions or comments?
Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

■ 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 PROTECTION. DO NOT USE IF SEALS ARE OPEN OR TORN.



Tear gum through foil.



Peel off backing starting at corner with loose edge.



To remove the gum, tear at single unit.

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.

All LEADER™ Brand Products Have A 100% Money Back Guarantee
 Return to place of purchase if not satisfied.

NDC 70000-0345-1

LEADER™

Sugar-Free

Nicotine Gum

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

2 mg

Original 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



Actual Size

50 PIECES, 2 mg EACH

COMPARE TO NICORETTE® ORIGINAL GUM active ingredient*

100% Money Back Guarantee

Drug Facts

Active ingredient (in each chewing piece) Nicotine polacrilex (equal to 2 mg nicotine)Stop smoking aid

Purpose

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

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

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DUBLIN, OHIO 43017
www.leader.com 1-800-200-6533
Essential to Care™ Since 1979
Product of Ireland

CIN 5420823 REV. 09/24
 0 96295 13383 7
 PLU-06198 F0080222

LEADER Sugar Free Nicotine Gum Original Flavor

Principal display panel 4 mg

COMPARE TO NICORETTE® ORIGINAL GUM active ingredient*

Sugar-Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

Stop Smoking Aid

4 mg

Original Flavor

For Those Who Smoke Their First Cigarette **With 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 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
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BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE OPEN OR TORN.

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

Package label 4 mg

Drug Facts (continued)

- 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 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

- each piece contains: calcium 110 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light.

Inactive ingredients acesulfame potassium, butylated hydroxytoluene, carnauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc

Questions or comments?
Call 1-877-753-3836 Monday-Friday 9AM-5PM EST

■ not for sale to those under 18 years of age
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BLISTER PACKAGED FOR USE BY INDIVIDUAL USERS. AGE CHECK ON TOP.

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.
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4. Use With a Support Program as directed in the enclosed User's Guide.

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Return to piece of purchase if not satisfied.

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DUBLIN, OHIO 43017
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Essential to Care™ since 1979
Product of Ireland

LEADER™

NDC 70000-0341-1

Sugar-Free

Nicotine Gum

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

4 mg

Original 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

COMPARE TO NICORETTE® ORIGINAL GUM active ingredient*

100% Money Back Guarantee

50 PIECES, 4 mg EACH

Drug Facts

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

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

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- using a non-nicotine stop smoking drug
- taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

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- mouth, teeth, or jaw problems occur
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Directions

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- 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

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LEADER Sugar Free Nicotine Gum Original Flavor

NICOTINE POLACRILEX ORIGINAL

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0345
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

ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white (off white to tan)	Score	no score
Shape	SQUARE	Size	14mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0345-1	50 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	ANDA074507	07/03/2018	

NICOTINE POLACRILEX ORIGINAL

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0341
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0341-1	50 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	ANDA074707	07/03/2018	

Labeler - Cardinal Health (Leader) 70000 (063997360)