

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

Nicotine Polacrilex Coated Ice Mint 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:

| 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 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® WHITE ICE MINT® GUM active ingredient*

Sugar-Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

Stop Smoking Aid

2 mg

Coated Ice 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 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, L.P., distributor of Nicorette® White Ice Mint® 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

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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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PLD-E616A
FC008094

LEADER[™]

NDC 70000-0348-1

Sugar-Free Nicotine Gum

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

2 mg

Coated Ice 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

COMPARE TO
NICORETTE®
COATED
WHITE ICE
MINT® GUM
active ingredient*

100% Money
Back Guarantee

20 PIECES, 2 mg EACH



Actual Size

CardinalHealth[™]

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DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6333
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.

■ 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



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) 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.

CIN 5420898 REV. 6/22



LEADER Sugar Free Nicotine Gum Ice Mint Flavor

Principal display panel 4 mg

COMPARE TO NICORETTE® WHITE ICE MINT® GUM active ingredient

Sugar-Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

Stop Smoking Aid

4 mg

Coated Ice 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

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 Lone 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

www.myleader.com

Package label 4 mg

TO INCREASE YOUR SUCCESS IN QUITTING:

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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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PLD-E622A
FC008105

LEADER

NDC 70000-0344-1

Sugar-Free

Nicotine Gum

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

4 mg

Coated Ice 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 WHITE ICE MINT® GUM active ingredient*

100% Money Back Guarantee

20 PIECES, 4 mg EACH

CIN 5420807 REV. 6/22



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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 hole.



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) **Purpose**
Nicotine polacrilex..... 4 mg (nicotine)..... Stop smoking aid

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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 Ice Mint Flavor

NICOTINE POLACRILEX COATED ICE MINT

nicotine polacrilex gum, chewing

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0348 |
| 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) | | | | |
| 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:70000-0348-1 | 20 in 1 CARTON | 07/03/2018 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:70000-0348-2 | 100 in 1 CARTON | 07/03/2018 | |
| 2 | | 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 | ANDA204794 | 07/03/2018 | | |

NICOTINE POLACRILEX COATED ICE MINT

nicotine polacrilex gum, chewing

| Product Information | | | |
|---------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0344 |

| | |
|--------------------------------|--------|
| 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:70000-0344-1 | 20 in 1 CARTON | 07/03/2018 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:70000-0344-2 | 100 in 1 CARTON | 07/03/2018 | |
| 2 | | 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 | ANDA204833 | 07/03/2018 | |

Revised: 6/2022

Cardinal Health (Leader) 70000