

NICOTINE POLACRILEX COATED MINT- nicotine polacrilex gum, chewing
Roman Health Ventures Inc.

Nicotine Polarilex Coated Mint 2 mg and 4 mg - Roman

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 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
- **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
- **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 and 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 and xylitol.

Questions or comments?

Call 1-877-440-7867

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 foil starting at corner with loose edge



Push gum through foil

Blister packaged for your protection.

Do not use if individual seals are open or torn.

- **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.**

FREE AUDIO CD
Upon Request.
See Inside.

Principal Display Panel - 2 mg

ZERO

Compare to the active ingredient in Nicorette[®] Fresh Mint[™] Coated Gum*

Sugar Free

Nicotine Polacrilex
Gum USP, 2 mg (nicotine)

Stop Smoking Aid

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

Coated Mint

160 Pieces, 2 mg Each

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.
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To remove the gum, tear off single unit.



Peel off backing starting at corner with loose edge.



Push gum through foil.

zero

Compare to the active ingredient in Nicorette® Fresh Mint™ Coated Gum*

Sugar Free

Nicotine Polacrilex Gum USP, 2 mg (nicotine)

Stop Smoking Aid

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

Coated Mint

Actual Size



2 mg

160 Pieces, 2 mg Each

zero

Sugar Free

Nicotine Polacrilex Gum USP, 2 mg (nicotine)

Stop Smoking Aid

Coated Mint

2 mg

Nicorette is a registered trademark of GlaxoSmithKline Consumer Healthcare, L.P. This product is not affiliated with GlaxoSmithKline Consumer Healthcare, L.P.



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FREE AUDIO CD
upon request. See inside.

Distributed by:
Roman Health Ventures
New York, New York 10003

<p>Drug Facts</p> <p>Active ingredient (in each chewing piece) Nicotine polacrilex, ... 2 mg (nicotine), ... Stop smoking aid</p> <p>Purpose associated with quitting smoking. reduces withdrawal symptoms, including nicotine craving.</p> <p>Use If you are pregnant or breastfeeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking. Nicotine is believed to be safer than smoking. However, the medicine is not for use in children who do not fully know.</p> <p>Warnings Ask a doctor before use if you have: • heart disease, recent heart attack, or angina • high blood pressure not controlled with medication. Nicotine can increase your heart rate. • Nicotine can increase your heart rate. • may increase blood pressure. • may interact with other medicines. • history of seizures • stomach ulcer or indigestion • can increase blood pressure. • taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted. • Stop use and ask doctor if: • you get symptoms of acute overdose such as nausea, vomiting, diarrhea, dizziness, weakness, and rapid heartbeat • you have symptoms of an allergic reaction (such as difficulty breathing or rash)</p> <p>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 right away.</p>	<p>Drug Facts (continued)</p> <p>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. • Do not use if you are pregnant or breastfeeding. • If you smoke your first cigarette within 30 minutes of waking up, use 2 mg nicotine gum more than 30 minutes after 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 1 to 2 hours 1 piece every 1 to 2 hours</p> <p>Other information • Nicotine gum is a medicine and must be used a certain way to get the best results. • Chew the gum slowly until it begins to melt. Then, park it between your cheek and gum. When the tongue begins to melt, begin chewing again, until the tongue returns. • Repeat this process until most of the tongue is gone (about 30 minutes). • Do not eat or drink for 15 minutes before chewing the nicotine gum or while chewing a piece. • Do not use for more than 24 pieces a day. • If you experience strong or frequent cravings, you may use Nicotine Polacrilex Gum USP, 4 mg (nicotine) gum. However, do not use more than 24 pieces a day. • It is important to complete treatment. If you feel you need to stop use for a longer period to keep from smoking, talk to your health care provider. • Each piece contains calcium 110 mg, sodium 6 mg.</p> <p>Questions or comments? Call 1-877-440-7887</p>
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Sugar Free
Nicotine Polacrilex
Gum USP, 2 mg (nicotine)
Stop Smoking Aid
Coated Mint

Blister packaged for your protection. Do not use if individual seals are open or torn.

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.

Principal Display Panel - 4 mg

ZERO

Compare to the active ingredient in Nicorette[®] Fresh Mint[™] Coated Gum*

Sugar Free

Nicotine Polacrilex
Gum USP, 4 mg (nicotine)

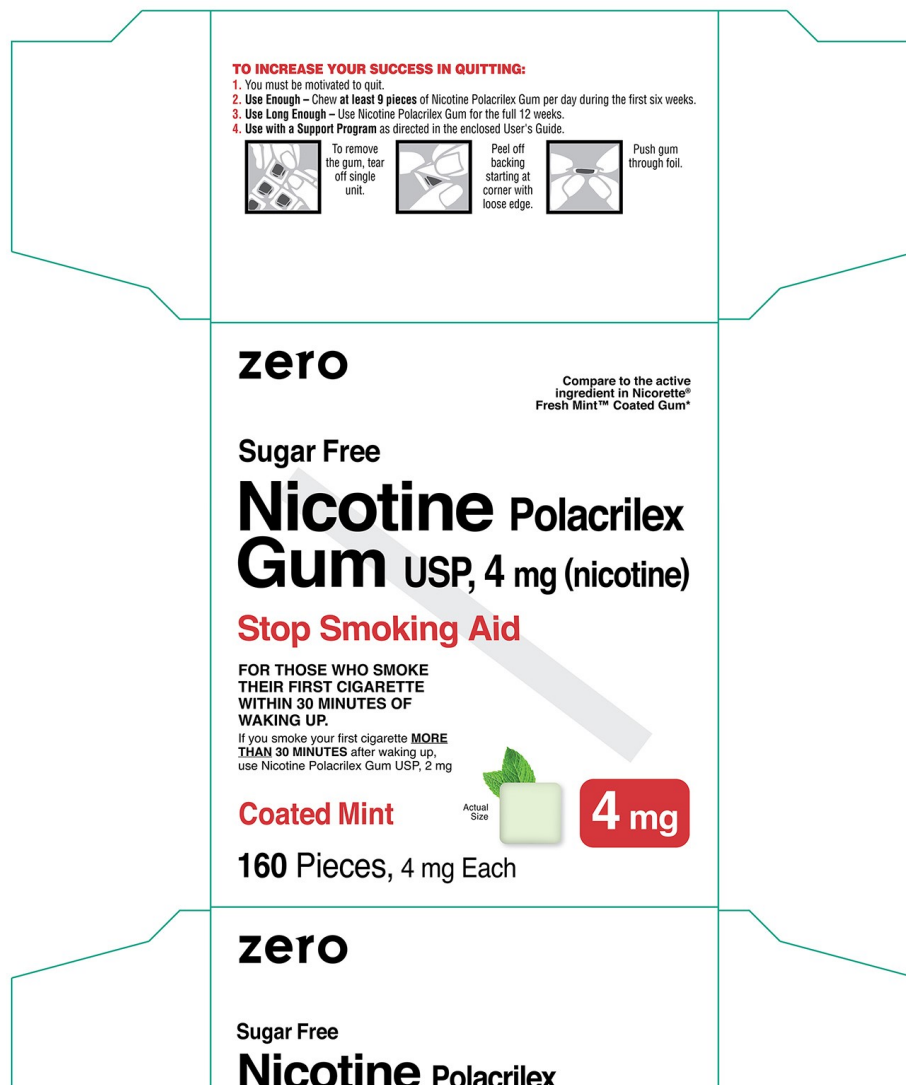
Stop Smoking Aid

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

Coated Mint

160 Pieces, 4 mg Each



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:72484-428-16	160 in 1 CARTON	10/08/2018	
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	10/08/2018	

NICOTINE POLACRILEX COATED MINT

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72484-429
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

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1	NDC:72484-429-16	160 in 1 CARTON	10/08/2018	
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078697	10/08/2018	

Labeler - Roman Health Ventures Inc. (081317350)

Revised: 10/2019

Roman Health Ventures Inc.