

NICOTINE- nicotine polacrilex gum, chewing
P & L Development, LLC

Nicotine Polacrilex Gum Coated Ice Mint 4 mg ANDA204833 - Equate

Drug Facts

Active ingredient (in each chewing piece)

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

- **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

- 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, FD&C blue #2, FD&C red #40, FD&C yellow #6, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide, xylitol.

Questions or comments?

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

Principal Display Panel

*Compare to the active ingredient in Nicorette® Gum

nicotine Gum

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, 2 mg

4 mg

sugar-free

coated fruit flavor

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivate 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 starting at corner with loose edge

Push gum through foil

- 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 INDIVIDUAL SEALS ARE OPEN OR TORN.

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

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Package Label

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 starting at corner with loose edge.



Push gum through foil.



nicotine gum
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

4 mg

sugar-free

coated fruit flavor

160 pieces, 4 mg each

*Compare to the active ingredient in Nicorette® Gum



nicotine gum
nicotine polacrilex gum USP, 4 mg (nicotine)
stop smoking aid

New
Wellness Basics - 4mg Nicotinal Symptoms - 160 Count



160-48219 1600009 Product of Poland

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

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to cause drowsiness and dizziness. They also pieces of gum in paper and throw away in the trash. Do not smoke, use alcohol, tobacco, or other nicotine products. If you are pregnant or breastfeeding, consult your doctor before using this product. Read the enclosed User's Guide for complete directions and other important information.
If you are under 18 years of age, ask a doctor before use.
If you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine gum.
If you have symptoms of an allergy, such as difficulty breathing or rash.
If regular treatment or prescriptions occur.
If you are pregnant or breastfeeding, consult your doctor before use.
If you are under 18 years of age, ask a doctor before use.
If you are pregnant or breastfeeding, consult your doctor before use.

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to cause drowsiness and dizziness. They also pieces of gum in paper and throw away in the trash. Do not smoke, use alcohol, tobacco, or other nicotine products. If you are pregnant or breastfeeding, consult your doctor before using this product. Read the enclosed User's Guide for complete directions and other important information.
If you are under 18 years of age, ask a doctor before use.
If you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine gum.
If you have symptoms of an allergy, such as difficulty breathing or rash.
If regular treatment or prescriptions occur.
If you are pregnant or breastfeeding, consult your doctor before use.
If you are under 18 years of age, ask a doctor before use.
If you are pregnant or breastfeeding, consult your doctor before use.

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to cause drowsiness and dizziness. They also pieces of gum in paper and throw away in the trash. Do not smoke, use alcohol, tobacco, or other nicotine products. If you are pregnant or breastfeeding, consult your doctor before using this product. Read the enclosed User's Guide for complete directions and other important information.
If you are under 18 years of age, ask a doctor before use.
If you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine gum.
If you have symptoms of an allergy, such as difficulty breathing or rash.
If regular treatment or prescriptions occur.
If you are pregnant or breastfeeding, consult your doctor before use.
If you are under 18 years of age, ask a doctor before use.
If you are pregnant or breastfeeding, consult your doctor before use.

Exp. Date:
Lot No.:



<p>Drug Facts</p> <p>Active ingredient (in each chewing piece) Nicotine polacrilex, 4 mg (nicotine)</p> <p>Purpose Stop smoking aid</p> <p>Use Nicotine withdrawal symptoms, including nicotine craving, associated with quitting smoking</p> <p>Warnings If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Cerebral artery narrowing may occur. Do not use this medicine without taking any nicotine replacement product. This medicine is intended to assist with smoking cessation. However, the risk to your child from this medicine may be higher than from smoking.</p> <p>Directions Ask a doctor before use if you have heart disease, recent heart attack, or regular heart pain. Nicotine can increase blood pressure. Ask a doctor before use if you are taking any medicine. Do not use this medicine if you are taking any medicine that may interact with nicotine. Nicotine can increase your heart rate.</p> <p>Other information Ask a doctor or pharmacist before use if you are taking a non-nicotine stop smoking drug. Nicotine polacrilex gum is not for use in children. Nicotine polacrilex gum is not for use in pregnant women or from any source where proof of age cannot be verified.</p>	<p>Drug Facts (continued)</p> <p>If you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine gum according to the following 12 week schedule:</p> <table border="1"> <tr> <td>Weeks 1 to 2</td> <td>1 piece every 2 to 4 hours</td> </tr> <tr> <td>Weeks 3 to 4</td> <td>1 piece every 4 to 8 hours</td> </tr> <tr> <td>Weeks 5 to 12</td> <td>1 piece every 8 to 12 hours</td> </tr> </table> <p>Use at least 9 pieces per day for the first 6 weeks. When the light is gone, begin chewing again, until the light returns. When the light returns, do not continuously use new pieces after another 15 minutes. If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Cerebral artery narrowing may occur. Do not use this medicine without taking any nicotine replacement product. This medicine is intended to assist with smoking cessation. However, the risk to your child from this medicine may be higher than from smoking.</p> <p>Other information Ask a doctor or pharmacist before use if you are taking a non-nicotine stop smoking drug. Nicotine polacrilex gum is not for use in children. Nicotine polacrilex gum is not for use in pregnant women or from any source where proof of age cannot be verified.</p>	Weeks 1 to 2	1 piece every 2 to 4 hours	Weeks 3 to 4	1 piece every 4 to 8 hours	Weeks 5 to 12	1 piece every 8 to 12 hours
Weeks 1 to 2	1 piece every 2 to 4 hours						
Weeks 3 to 4	1 piece every 4 to 8 hours						
Weeks 5 to 12	1 piece every 8 to 12 hours						

WELLNESS BASICS Nicotine Gum Coated Fruit Flavor

NICOTINE

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-913
Route of Administration	ORAL		

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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	brown (light tan)	Score	no score
Shape	SQUARE	Size	14mm

Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-913-16	160 in 1 CARTON	03/01/2024	
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	03/01/2024	

Labeler - P & L Development, LLC (800014821)