

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

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 your 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 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 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 the process until most of the tingle is gone (about 30 minutes)
- do not eat or drink 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 **1-877-753-3935** 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 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**
 - **not for sale in vending machines or from any source where proof of age cannot be required**

*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

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Package Label

See inside for more details or visit www.wellnessbasics.com

Do not use if you are pregnant or breastfeeding.
Do not use if you are under 18 years of age.
Do not use if you are allergic to nicotine or any of the other ingredients.

WARNING: Nicotine is highly addictive and can be fatal if misused.

<p>Drug Facts (continued)</p> <p>It may reduce your risk of getting a heart disease, stroke, or other complications if you quit smoking now. However, you may use a second pack within the first 12 weeks. However, do not continue to use the gum after the 12 weeks.</p> <p>If you have a heart condition, you may use a second pack within the first 12 weeks. However, do not continue to use the gum after the 12 weeks.</p> <p>If you have a heart condition, you may use a second pack within the first 12 weeks. However, do not continue to use the gum after the 12 weeks.</p> <p>If you have a heart condition, you may use a second pack within the first 12 weeks. However, do not continue to use the gum after the 12 weeks.</p>	<p>Drug Facts</p> <p>Warnings</p> <p>If you are pregnant or breastfeeding, only use this medicine on the advice of your health care provider. Smoking can reduce the effectiveness of your medicine. Do not use this medicine if you are pregnant or breastfeeding.</p> <p>If you are pregnant or breastfeeding, only use this medicine on the advice of your health care provider. Smoking can reduce the effectiveness of your medicine. Do not use this medicine if you are pregnant or breastfeeding.</p> <p>If you are pregnant or breastfeeding, only use this medicine on the advice of your health care provider. Smoking can reduce the effectiveness of your medicine. Do not use this medicine if you are pregnant or breastfeeding.</p>
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WELLNESS BASICS Nicotine Gum Uncoated Original Flavor

NICOTINE
 nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-935
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
SORBITOL (UNII: 506T60A25R)	
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)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-935-17	170 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	ANDA074707	03/01/2024	

Labeler - P & L Development, LLC (800014821)

Revised: 3/2024

P & L Development, LLC