

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

Nicotine Polacrilex Gum 2 mg and 4 mg Coated Fruit - Rugby

Drug Facts

Active ingredient (in each chewing piece)

Nicotine Polacrilex 2 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.

Other information - 2 mg

- **each piece contains:** calcium 115 mg, sodium 8 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients - 2 mg

acacia, acesulfame potassium, carnauba wax, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, 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 - 2 mg

*Compare to the active ingredient of Nicorette® Gum

Nicotine Gum

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

2 mg

sugar-free

coated fruit flavor

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 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 2 mg

See links for more details or visit www.wellnessb.com.

Not for sale to those under 18 years of age
 a proof of age required
 sources without proof of age cannot be verified

WELLNESS BASICS NICOTINE GUM COATED FRUIT FLAVOR

Drug Facts (continued)

Warnings

- Do not use if you are pregnant, breastfeeding, or planning to become pregnant, as nicotine may harm the fetus or infant.
- Do not use if you are taking or plan to take any medicine that may interact with nicotine gum, including antidepressants, anti-anxiety medications, and certain blood pressure medications.
- Do not use if you are taking or plan to take any medicine that may interact with nicotine gum, including anti-arrhythmics, anti-depressants, anti-anxiety medications, and certain blood pressure medications.
- Do not use if you are taking or plan to take any medicine that may interact with nicotine gum, including anti-arrhythmics, anti-depressants, anti-anxiety medications, and certain blood pressure medications.

Directions

Chew the gum for 15 minutes. Do not swallow. Spit out the gum and discard. Do not eat or drink for 15 minutes after chewing the gum. Do not use more than 16 pieces per day. Do not use for more than 12 weeks.

Other Information

Keep out of reach of children. Use only as directed. Do not use if you are pregnant, breastfeeding, or planning to become pregnant, as nicotine may harm the fetus or infant.

nicotine gum
 USP, 2 mg (nicotine)
 stop smoking aid



WELLNESS BASICS Nicotine Gum Coated Fruit Flavor

NICOTINE

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-592
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: 230V73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM OXIDE (UNII: 3A3U0G171G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FX9V2JJP)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	brown (light brown)	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:59726-592-16	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	ANDA079044	03/01/2024	

Labeler - P & L Development, LLC (800014821)

Revised: 7/2024

P & L Development, LLC