

**NICOTINE- nicotine polacrilex gum, chewing
QUALITY CHOICE (Chain Drug Marketing Association)**

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 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. If you need to remove the lozenge, wrap it 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. No studies have been done to show if this product will work for you.**
- 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 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 115 mg, sodium 11 mg
- store at 20-25°C (68-77°F)
- protect from light

Inactive ingredients

acesulfame potassium, butylated hydroxytoluene, carnauba wax, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc

Questions or comments?

Call **1-800-935-2362** Monday-Friday 9AM-5PM EST

Principal Display Panel

*Compare to the active ingredient of Nicorette® Gum

Nicotine Gum

Stop Smoking Aid

Nicotine polacrilex gum USP, 2 mg (nicotine)

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** after waking up, use Nicotine Polacrilex Gum USP, 4 mg

2 mg Sugar-free

UNCOATED ORIGINAL FLAVOR

TO INCREASE YOUR SUCCESS IN QUITTING:

- 1.** You must be motivated to quit.
- 2.** Use Enough - Use **at least 9** 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**

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® *mini* Lozenge.

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

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE OPEN OR TORN

Distributed by C.D.M.A., Inc. ©

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

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.



NDC 63868-849-11

*Compare to the Active Ingredient in Nicorette® Gum

Nicotine Gum

Stop Smoking Aid

2 mg

Sugar-free

UNCOATED ORIGINAL FLAVOR



actual size

Nicotine polacrilex gum USP, 2 mg (nicotine)

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

110 Pieces, 2 mg EACH



Nicotine Gum

Stop Smoking Aid

Nicotine polacrilex gum USP, 2 mg (nicotine)



Polacrilex Gum USP, 4 mg

inactive ingredients acetaminophen, benzocaine, butylated hydroxytoluene, croscarmellose, gum base, sodium benzoate, sodium carbonate, sodium saccharin, sucralose, xanthan gum.

Questions or comments?
Call 1-800-955-2362 Monday-Friday 9AM-5PM EST

Distributed by C.D.M.A., Inc.
4317 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-955-2362

100% SATISFACTION GUARANTEED

Healthcare, LP, distributor of Nicorette® Gum.
*This product is not manufactured or distributed by GaySkinline Consumer

Directions
If you are under 18 years of age, ask a doctor before use.
Before using the 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 of waking up, use 2 mg nicotine gum.

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Keep used pieces of gum in a 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.

Warnings
If you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat.
If you get 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. Keep used pieces of gum in a 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.

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

REUSE PACKAGED FOR YOUR PROTECTION, DO NOT USE IF

Drug Facts	<p>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.</p> <p>Ask a doctor before use if you have a sudden-onset chest pain, irregular heartbeat, nicotine can increase 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. dizziness, lightheadedness, or fainting. Ask a doctor or pharmacist before use if you are taking prescription medicine for depression or asthma, your prescription dose may need to be adjusted.</p>
Use	<p>nicotine gum as a medicine and that he used a certain way to get the best results. chew the gum slowly until it dissolves. Then park it between your cheek and gum. When the process is gone, begin chewing again, until the right number of pieces are gone. Do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece. If you experience strong or frequent craves, you may use a second piece within the hour. However, do not continuously use one piece after another when the hour. However, do not continuously use one piece after another when the hour. However, do not continuously use one piece after another when the hour. However, do not continuously use one piece after another when the hour. However, do not continuously use one piece after another when the hour.</p>
Other Information	<p>each piece contains: each piece 15 mg, sodium 11 mg Store at 20° to 25°C (68° to 77°) protect from light.</p>
Drug Facts (continued)	<p>Drug Facts use 2 mg nicotine gum according to the following 12 week schedule: Weeks 1 to 6: 1 piece every 4 to 6 hours Weeks 7 to 9: 1 piece every 2 hours Weeks 10 to 12: 1 piece every 1 to 2 hours</p>

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, you are at a higher risk of developing heart disease and lung disease. Nicotine gum can help you quit smoking and reduce your risk of developing these diseases.

Nicotine polacrilex gum USP, 2 mg (nicotine)

Stop Smoking Aid

Nicotine Gum

Compare to the Active Ingredient in Nicorette® Gum

QUALITY CHOICE

NDC 63868-849-11

QUALITY CHOICE Nicotine Gum Uncoated Original Flavor

NICOTINE

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-849
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM BICARBONATE (UNII: 8MDF5V39Q0)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white (off white tan)	Score	no score
Shape	SQUARE	Size	14mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-849-11	110 in 1 CARTON	01/29/2021	01/31/2025
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	ANDA074507		01/29/2021	01/31/2025

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 5/2023

QUALITY CHOICE (Chain Drug Marketing Association)