

**NICOTINE- nicotine polacrilex gum, chewing**  
**Rite Aid Corporation**

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**Drug Facts**

**Active ingredient (in each chewing piece)**

Nicotine polacrilex 2 mg

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

## Principal Display Panel

Compare to the active ingredient of Nicorette® Gum\*

### Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (nicotine)

Stop Smoking Aid

Sugar free uncoated nicotine gum

ORIGINAL FLAVOR

PIECES 2 MG EACH

**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

**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](http://www.nitthehabit.com)**

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


**DISTRIBUTED BY:**

RITE AID, 30 HUNTER LANE,

CAMP HILL, PA 17011

[www.riteaid.com](http://www.riteaid.com)

**Package Label**



The image shows a portion of a blue and white package label for Nicotine Gum. At the top, it reads "TO INCREASE YOUR SUCCESS IN QUITTING:" followed by four numbered instructions: 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. Below the text are three small illustrations: the first shows a hand tearing a unit from a blister pack; the second shows a hand peeling the backing from a corner; the third shows a hand pushing a unit through a foil wrapper. Below these are three small text boxes: "To remove the gum, tear off single unit.", "Peel off backing starting at corner with loose edge.", and "Push gum through foil." At the bottom of the label, it says "Compare to the active ingredient of Nicorette® Gum\*" and "NDC 11822-3328-3". The word "Nicotine" is printed in large white letters, and "Gum" is partially visible below it. On the right side, there is a white hexagonal shape containing the number "2" and "mg" below it.

**4 mg**

**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  
sugar free uncoated nicotine gum



ACTUAL SIZE  
ORIGINAL FLAVOR  
**110**  
PIECES 2 mg EACH

Compare to the active ingredient of Nicorette® Gum\* NDC 11822-3328-3

**Nicotine  
Gum**

**2  
mg**

**Nicotine Polacrilex Gum USP,  
2 mg (nicotine)  
Stop Smoking Aid**

**SATISFACTION  
GUARANTEE**  
If you're not satisfied, we'll  
happily refund your money.

**DISTRIBUTED BY:**  
RITE AID, 30 HUNTER LANE,  
CAMP HILL, PA 17011  
www.riteaid.com

\*The product is not manufactured or distributed by transdermal  
Consumer Healthcare, L.P., distributor of Nicorette® Gum.

**Drug Facts (continued)**

**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 with long-acting replacement medicine. The nicotine in gum, when the label is gone, begins changing again, and the higher the dose, the longer the gum slowly until it begins. Then park it between your cheek and teeth.

**Use**  
Nicotine polacrilex... 2 mg (nicotine) ... Stop smoking aid

**Other information**  
Each piece contains calcium 115 mg, sodium 11 mg  
Store at 20°-25°C (68°-77°)  
Keep from light

**Questions or comments?**  
Call 1-877-752-9936 Monday-Friday 9AM-9PM EST



THEFT-SURVEILLANCE TAG AREA

**FOR THOSE WHO SMOKE  
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  
sugar free uncoated nicotine gum

**Nicotine  
Gum**  
2 mg (nicotine)  
Nicotine Polacrilex Gum USP,  
Stop Smoking Aid

**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**

NEVER PACKAGES FOR YOUR PROTECTION. DO NOT USE IF  
NEAR EXPIRATION DATE OR OPEN ON TOP.

# NICOTINE

nicotine polacrilex gum, chewing

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-3328
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3328-3	110 in 1 CARTON	01/31/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-3328-4	170 in 1 CARTON	01/31/2020	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA074507	01/31/2020	

**Labeler** - Rite Aid Corporation (014578892)

