

**NICOTINE POLACRILEX- nicotine polacrilex gum, chewing**  
**Chain Drug Consortium, LLC**

-----  
**Nicotine Polacrilex Gum 2 mg - 4 mg Coated Ice Mint**

***Drug Facts***

***Active ingredient (in each chewing piece) - 2 mg***

Nicotine Polacrilex 2 mg (nicotine)

***Active ingredient (in each chewing piece) - 4 mg***

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 - 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:

<b>Weeks 1 to 6</b>	<b>Weeks 7 to 9</b>	<b>Weeks 10 to 12</b>
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.

**Directions - 4 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 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:

<b>Weeks 1 to 6</b>	<b>Weeks 7 to 9</b>	<b>Weeks 10 to 12</b>
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

**Other information - 4 mg**

- **each piece contains:** calcium 120 mg, sodium 8 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

**Inactive ingredients - 2 mg**

acacia, acesulfame potassium, carnauba wax, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium

dioxide and xylitol.

### **Inactive ingredients - 4 mg**

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 aluminum lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide and xylitol.

### **Questions or comments?**

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

### **Principal display panel 2mg**

COMPARE TO THE ACTIVE INGREDIENT IN NICORETTE® GUM\*

Sugar Free

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, use Nicotine Polacrilex Gum USP, 4 mg.

COATED ICE MINT 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 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 source where proof of age cannot be verified

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

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

Distributed By:

Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, PA 19087

**Package label 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.



To remove the gum, tear off single unit.



Peel off backing starting at corner with loose edge.



Push gum through foil.



COMPARE TO THE ACTIVE INGREDIENT IN NICORETTE® GUM\*

**2 mg**

**Sugar Free**  
**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.

**COATED ICE MINT**

100 PIECES, 2 mg EACH



**Nicotine Polacrilex**  
**Gum USP, 2 mg (nicotine)**  
**STOP SMOKING AID**  
**COATED ICE MINT**

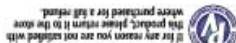


PLD-016A FC00571

See inside for more details or visit [www.nixthethabit.com](http://www.nixthethabit.com).

THEFT SURVEILLANCE TAG AREA

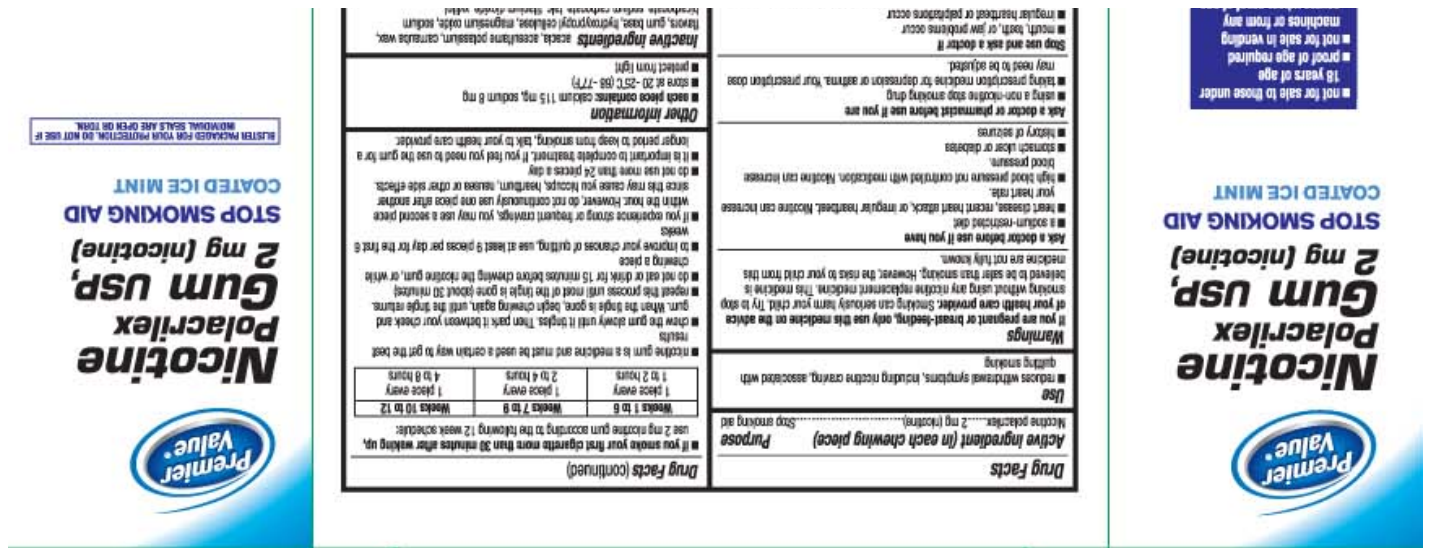
Source within proof of age cannot be verified



If any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.  
 Distributed By:  
 Pharmacy Value Alliance, LLC  
 407 East Lancaster Avenue,  
 Wynm, PA 19087

\*This product is not manufactured or distributed by Chas. B. Williams Consumer Healthcare, L.P., distributor of Nicorette® Gum.  
 Call 1-877-753-3808 Monday-Friday 9AM-5PM EST  
**Questions or comments?**

**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 within 30 minutes of waking up, use 4 mg nicotine gum.  
**Keep out of reach of children and pets.** Pieces of nicotine gum may have a sharp taste 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.  
 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.



**PREMIER VALUE Sugar Free Nicotine Gum Ice Mint Flavor**

**Principal display panel 4 mg**

COMPARE TO THE ACTIVE INGREDIENT IN NICORETTE® GUM\*

Sugar Free

Nicotine Polacrilex Gum USP, 4 mg (nicotine)

**STOP SMOKING AID**

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette MORE THAN 30 MINUTES after waking up, us Nicotine Polacrilex Gum USP, 2 mg

COATED ICE MINT 4 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 verified.

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

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

Distributed By:

Pharmacy Value Alliance, LLC  
407 East Lancaster Avenue,  
Wayne, PA 19087

**Package label 4 mg**







**PREMIER VALUE Sugar Free Nicotine Ice Mint Flavor**

**NICOTINE POLACRILEX**

nicotine polacrilex gum, chewing

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-292
<b>Route of Administration</b>	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: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM OXIDE (UNII: 3A3U0G171G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>	MINT (coated ice mint)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:68016-292-44	100 in 1 CARTON	10/01/2017	
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	ANDA204794	10/01/2017	

## NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-293
Route of Administration	BUCCAL		

### 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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

### Product Characteristics

Color	yellow	Score	no score
Shape	SQUARE	Size	14mm
Flavor	MINT (coated ice mint)	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-293-44	100 in 1 CARTON	10/01/2017	
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	ANDA204833	10/01/2017	

**Labeler** - Chain Drug Consortium, LLC (101668460)

Revised: 11/2022

Chain Drug Consortium, LLC