

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

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**Nicotine Polacrilex Gum 2 mg and 4 mg Original Flavor - Premier Value (Chain Drug Consortium, LLC)**

***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 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

**Other information - 4 mg**

- **each piece contains:** calcium 110 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

**Inactive ingredients - 2 mg**

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

**Inactive ingredients - 4 mg**

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 2 mg

COMPARE TO THE ACTIVE INGREDIENT IN NICORETTE® 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, 4mg

ORIGINAL 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 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 286**



**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**

# 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

**ORIGINAL**



actual size

110 PIECES, 2 MG EACH



# Nicotine Polacrilex Gum USP, 2 mg (nicotine)

## STOP SMOKING AID

### ORIGINAL



NOT for sale in vending machines or from any source where proof of age cannot be verified.  
Theft surveillance tag area

**active ingredients** acetylcholine potassium, oxidized hydroxytoluene, menthyl salicylate  
contains water, flavors, gum base, sodium bicarbonate, sodium carboxymethylcellulose  
**Questions or comments?**  
Call 1-877-753-8655 Monday-Friday 9AM-5PM EST

**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 Polacrilex Gum  
Keep out of reach of children and pets. Pieces of nicotine gum may have enough residue to make children and pets sick. When 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.  
If you have symptoms of an allergic reaction (such as difficulty breathing or rash), dizziness, weakness, and rapid heartbeat  
If you get symptoms of nicotine overdose such as nausea, vomiting, diarrhea, rapid heartbeat or palpitations occur  
Do not chew, suck, or swallow pieces of gum



Distributed By:  
Pharmacia Value Alliance, LLC  
407 East Lancaster Avenue,  
Wayne, PA 19087

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If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

SLIGHTLY PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INTERNAL SEAL IS OPEN OR TORN.

**Nicotine**  
**Polacrilex**  
**Gum USP,**  
**2 mg (nicotine)**  
**STOP SMOKING AID**  
**ORIGINAL**



**Drug Facts**

**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 sudden-onset chest pain, heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.

■ Light blood pressure not controlled with medication. Nicotine can increase blood pressure.

■ History of seizure.

■ Taking a non-nicotine drug for depression or anxiety. Your prescription dose may need to be adjusted.

**Use**

■ Nicotine withdrawal symptoms (including nicotine craving, associated with quitting smoking)

**Active ingredient (in each chewing piece)**  
 Nicotine (nicotine) 2 mg (nicotine)

**Purpose**  
 Stop smoking aid

**Other information**

■ Each piece contains cinnabarin 115 mg, sodium 11 mg

■ Store at 20°-25°C (68°-77°F)

■ Protect from light

**Drug Facts (continued)**

■ 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	1 piece every 1 to 2 hours
Weeks 7 to 9	1 piece every 2 to 4 hours
Weeks 10 to 12	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 begins to melt. Then park it between your cheek and gum. When the bubble is gone, begin chewing again, until the taste returns.

■ Repeat this process until most of the gum is gone (about 30 minutes).

■ Do not eat or drink for 15 minutes before chewing the nicotine gum, or within 1 hour after chewing.

■ Do not use more than 24 pieces a day.

■ It is important to complete treatment. If you find you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

■ If you experience dizziness or frequent vomiting, you may use a second piece within the 15 minute period. However, do not continuously use one piece after another since this may cause you dizziness, headache, nausea or other side effects.

■ Do not use more than 24 pieces a day.

■ It is important to complete treatment. If you find you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

**PREMIER VALUE Nicotine Gum Original Flavor**

Package label 282

■ Not for sale to those under 18 years of age.  
 ■ Proof of age required.

**Nicotine**  
**Polacrilex**  
**Gum USP,**  
**2 mg (nicotine)**  
**STOP SMOKING AID**  
**ORIGINAL**







**PREMIER VALUE nicotine Gum Original Flavor**

**Principal display panel 4 mg**

COMPARE TO THE ACTIVE INGREDIENT IN NICORETTE® 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 MOREW THAN 30 MINUTES after waking up, use Nicotine Polacrilex Gum USP, 2 mg

ORIGINAL 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 SEALS ARE OPEN OR TORN.

Distributed by:

Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, PA 19087

**Package label 4 mg 287**

**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\*

**4 mg**

# 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

**ORIGINAL**



actual size

110 PIECES, 4 MG EACH



# Nicotine Polacrilex Gum USP, 4 mg (nicotine)

## STOP SMOKING AID

**ORIGINAL**



FDL0835A F00370H

NOT FOR SALE IN VERMONT  
 machines or from any  
 source where proof of  
 theft surveillance  
 tag area

**Important information:** Nicotine Polacrilex Gum USP, 4 mg, FDAC and 4 mg, FDAC, contains wax, butyl rubber, gum base, sodium bicarbonate, sodium carbonate, and other inactive ingredients. © 2005 Nicotine Polacrilex Gum USP, 4 mg, FDAC, and 2 mg, FDAC, are trademarks of Nicotine Polacrilex Gum USP, 4 mg, FDAC, and 2 mg, FDAC, respectively. All other trademarks are the property of their respective owners.

**Questions or comments?**  
 Call 1-877-753-8855 Monday-Friday 9AM-5PM EST.

**Distributed by:**  
 Pharmacia Value Alliance, LLC  
 407 East Lancaster Avenue,  
 Wayne, PA 19087

**If any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.**

**Directions**

If you are under 18 years of age, use a doctor before use.

If you are 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.

**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.

**Do not use if you have symptoms of an allergic reaction (such as difficulty breathing or rash), dizziness, weakness, and rapid heartbeat.**

**Do not use if you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, or fainting.**

**Do not use if you have problems with your heart, liver, or jaw problems occur.**

**Do not use if you are pregnant or breastfeeding.**





**PREMIER VALUE Nicotine Gum Original Flavor**

**NICOTINE POLACRILEX, ORIGINAL**

nicotine polacrilex gum, chewing

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-282
<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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

**Product Characteristics**

Color	white (off-white to 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:68016-282-50	5 in 1 CARTON	09/01/2013	09/30/2018
1		10 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	09/01/2013	09/30/2018

**NICOTINE POLACRILEX, ORIGINAL**

nicotine polacrilex gum, chewing

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-286
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

**Product Characteristics**

Color	white (off-white to 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:68016-286-62	11 in 1 CARTON	07/01/2013	
1		10 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	07/01/2013	

**NICOTINE POLACRILEX, ORIGINAL**

nicotine polacrilex gum, chewing

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-283
Route of Administration	BUCCAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)		NICOTINE	4 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
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)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SODIUM CARBONATE (UNII: 45P3261C7T)				
SORBITOL (UNII: 506T60A25R)				
TALC (UNII: 7SEV7J4R1U)				
<b>Product Characteristics</b>				
Color	yellow (yellowish)	Score	no score	
Shape	SQUARE	Size	14mm	
Flavor		Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-283-50	5 in 1 CARTON	07/01/2013	10/31/2018
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074707	07/01/2013	10/31/2018	

## NICOTINE POLACRILEX, ORIGINAL

nicotine polacrilex gum, chewing

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-287
Route of Administration	BUCCAL		



**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

**Product Characteristics**

<b>Color</b>	yellow (yellowish)	<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:68016-287-62	11 in 1 CARTON	06/01/2013	
1		10 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	06/01/2013	

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