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

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:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every	1 piece every	1 piece every
1 to 2 hours	2 to 4 hours	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:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every	1 piece every	1 piece every
1 to 2 hours	2 to 4 hours	4 to 8 hours

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- 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 <u>WITHIN</u> 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.

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

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

TO INCREASE YOUR SUCCESS IN QUITTING:

- 1. You must be motivated to guit.
- 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*



Nicotine Polacrilex Gum USP, 2 mg (nicotine)

STOP SMOKING AID

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

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ORIGINAL

110 PIECES, 2 MG EACH







STOP SMOKING AID ORIGINAL

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Cal 1-877-753-3805 Monday-Friday 9/M-5PM EST Guestions of commisents?

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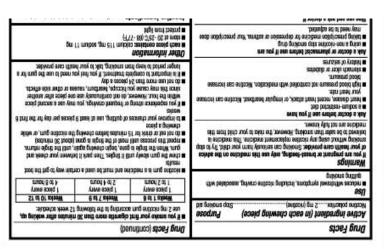
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machines or from any source where proof of age cannot be verified Mot for sale in vending





■ Proof of age required.

■ Not for sale to those

STOP SMOKING AID

2 mg (nicotine)

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Micotine

Polacrilex

ORIGINAL

under 18 years of age.

PREMIER VALUE Nicotine Gum Original Flavor

Package label 282



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.
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- 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:

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- 2. Use Enough Chew at least 9 pieces of Nicotine Polacrilex Gum per day during the first six weeks.
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- 4. Use with a Support Program as directed in the enclosed User's Guide.



To remove the gum, tear off single



Peel off backing starting at corner with loose edge.



Push gum through foil.







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

110 PIECES, 4 MG EACH



actual size





STOP SMOKING AID

ORIGINAL

If for any reason you are not same, this product, please return it is the where parchased for a full refund.

Pharmacy Value Alliance, LLC 407 East Lancaster Avenue, Wayne, PA 19067

"This product is not manufactured or distributed by GlacoSmithGins Con Healthcarr, L.P., distributor of Miconstor" Gum.

CAI 1-877-753-3835 Monday-Friday SAM-SPM EST

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USB — relaces withdrawal symptome, including nicotine crawing, associated with quitting smeking

Active ingredient (in each chewing piece) Acotne polecies. . . . mg (victine)

Drug Facts

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PREMIER VALUE Nicotine Gun Original Flavor

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Package label 4 mg 283



PREMIER VALUE Nicotine Gum Original Flavor

NICOTINE POLACRILEX, ORIGINAL nicotine polacrilex gum, chewing Product Information Product Type HUMAN OTC DRUG BUCCAL 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: 230V73Q5G9)		
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	
	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 Application Number or Monograph Marketing Start Marketing Category Citation Date 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: 230V73Q5G9)			
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				

P	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	12/31/2026	

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: 6	M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
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)	

Product Characteristics				
Color	yellow (yellowish)	Score	no score	
Shape	SQUARE	Size	14mm	
Flavor		Imprint Code		
Contains				

F	Packaging				
#	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			

Marketing Information				
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		
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 ma		

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
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)		

Product Characteristics						
Color	yellow (yellowish)	Score	no score			
Shape	SQUARE	Size	14mm			
Flavor		Imprint Code				
Contains						

P	Packaging					
#	tem 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	12/31/2026		

Labeler - Chain Drug Consortium, LLC (101668460)