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 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:

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

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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 - 25ºC (68 - 77ºF)
- protect from light

Other information - 4 mg

- **each piece contains:** calcium 110 mg, sodium 11 mg
- store at 20 - 25ºC (68 - 77ºF)
- 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*

Premier Value®

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

Premier Value®

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

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

- **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 for 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,
Wayne, PA 19087

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Questions or comments?
Call 1-877-753-3826 Monday-Friday 9AM-5PM EST

Inactive ingredients acesulfame potassium, hydrated hydroxylated carnauba wax, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc

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

Distributed by:

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407 East Lancaster Avenue,

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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.
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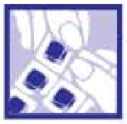
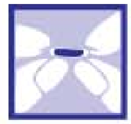
4. **Use with a Support Program** as directed in the enclosed User's Guide.



To remove the gum, tear off single unit.

Peel off backing starting at corner with loose edge.



Push gum through foil.

COMPARE TO THE ACTIVE INGREDIENT IN NICORETTE® GUM*

Premier Value®

4 mg

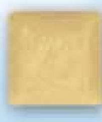
Nicotine Polacrilex Gum USP, 4 mg (nicotine)

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

Premier Value®

Nicotine Polacrilex Gum USP, 4 mg (nicotine)

STOP SMOKING AID

ORIGINAL

■ 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

■ **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

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?

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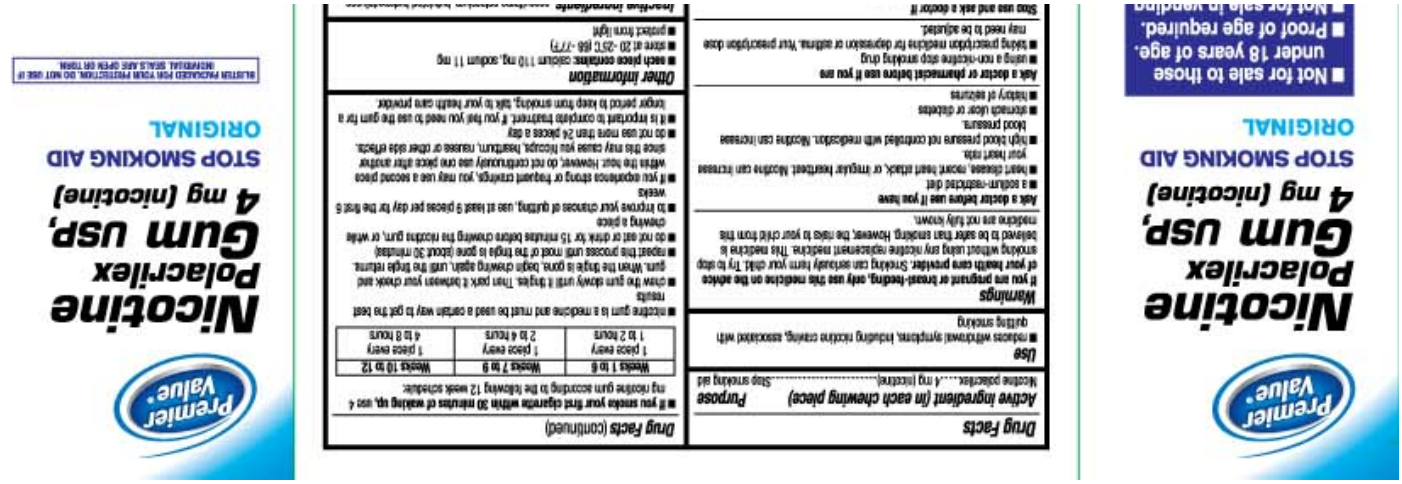
Theft surveillance tag area

PLD-C825A FC007604

8 40986 02988 2



PREMIER VALUE Nicotine Gun Original Flavor

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	**Item Code (Source)**	NDC:68016-282
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:68016-282-50	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	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: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

Inactive Ingredients

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)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-283-50	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 mg

Inactive Ingredients

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)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-287-62	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)

Revised: 6/2025 Chain Drug Consortium, LLC