

**NICOTINE- nicotine polacrilex gum, chewing  
Sam's West, Inc.**

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**Nicotine Gum Original Flavor**

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

Nicotine Polacrilex.....2 mg (nicotine)

Nicotine Polacrilex.....4 mg (nicotine)

**Purpose**

Stop smoking aid

**Use**

- Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

**Warnings**

**Pregnancy/Breastfeeding**

**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 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 instructions 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 in 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 instructions 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 in 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
- **(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 and 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 and talc.

#### **Questions**

**Questions or comments? Call 1-877-440-7867**

#### **Additional Information Found on Packaging**

**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.

Blister packaged for your protection.

**Do not use if individual seals are open or torn.**

- 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.

Distributed by:

Sam's West, Inc.

Bentonville, AR 72716

DP22504

DP22755

**Principal Display Panel**

Compare to Nicorette® Gum

active ingredient\*

NDC 68196-010-02

Member's Mark™

2 mg

Original Flavor

**Sugar Free**

**Nicotine Gum**

Nicotine Polacrilex Gum USP, (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

actual size  
Original Flavor

396  
Pieces

\*Nicorette® is a registered trademark of GlaxoSmithKline Consumer Healthcare, L.P.  
This product is not affiliated with GlaxoSmithKline Consumer Healthcare, L.P.

DP22504

**Drug Facts**

**Active ingredient:** Nicotine Polacrilex, 2 mg (nicotine) - 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 over time may lower your ability. Do not smoke or drink alcohol while using any nicotine replacement products. This medicine is intended to be used for short-term relief. However, the risk to your child from the medicine is not fully known.

**Ask a doctor before use if you have:**

- a heart condition, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medicine.
- Nicotine can increase blood pressure.
- ulcerative colitis or diabetes.
- history of seizures.

**Ask a doctor or pharmacist before use if you are:**

- taking a non-nicotine stop smoking drug.
- taking prescription medicine for depression or anxiety. Your physician should may require be adjusted.

**Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Do not use contents of gum in water and throw away or trash. In case of overdose, get medical help or contact Poison Control Center right away.**

**Directions:**

- If you are under 18 years of age, ask a doctor before use.
- Before using this product, read the Nicotine Gum's Guide to complete the steps 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 2	Weeks 3 to 4	Weeks 5 to 12
2 pieces every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

**Other information:**

- each piece contains nicotine of 2 mg, nicotine is 11 mg when at 20° - 25°C (68°-77°F) and less than 1 mg when at 30° - 35°C (86°-95°F).

**Active ingredients:** nicotine polacrilex, nicotine gum base, sorbitol, saccharin, sodium saccharin, sorbitol, and water.

**Questions or comments?** Call 1-877-446-7867

**Compare to Nicorette® Gum active ingredient\***

**Member's Mark**

**2 mg**

**Original Flavor**

**Sugar Free Nicotine Gum**

**Nicotine Polacrilex Gum USP (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.**

**actual size Original Flavor 396 Pieces**

**Nicotine Gum**

**Nicotine Polacrilex Gum USP (nicotine)**

**Stop Smoking Aid**

**2 mg**

**Nicotine Polacrilex Gum USP 2 mg Original DP22504**

**Principal Display Panel**

Compare to Nicorette® Gum  
active ingredient\*

NDC 68196-011-02

Member's Mark™

4 mg

Original Flavor

**Sugar Free**

**Nicotine Gum**

Nicotine Polacrilex Gum USP, (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

actual size

Original Flavor

396

Pieces

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This product is not affiliated with GlaxoSmithKline Consumer Healthcare, L.P.

DP22755

DP22756



**TO INCREASE YOUR SUCCESS IN QUITTING:**  
 1. Take your first cigarette at least 30 minutes after waking up during the first 12 weeks.  
 2. Chew Nicotine Gum at least 3 pieces of Nicotine Polacrilex Gum USP for the first 12 weeks.  
 3. Take your first cigarette at least 30 minutes after waking up during the first 12 weeks.  
 4. Take your first cigarette at least 30 minutes after waking up during the first 12 weeks.

**Drug Facts**

**Active Ingredient (in each chewing piece)**  
 Nicotine Polacrilex 4 mg (nicotine) 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 doses may need to be adjusted.

**Stop use and ask a doctor if**  
 • mouth, belly, 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 right away.

**Drug Facts (continued)**

**Directions**  
 • If you are under 18 years of age, ask a doctor before use before using this product. Read the enclosed Member's Guide for complete instructions 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

- nicotine gum is a medicine and must be used in a certain way to get the best results
- chew the gum slowly until it tingles. Then perk 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 8 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 110 mg, sodium 11 mg above at 20° - 25° C (68° - 77° F) - protect from light

**Inactive ingredients** acacia, caffeine, potassium, polydiallyl methacrylate, camphor, wax, FD&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 and talc.

**Questions or comments?** Call 1-877-440-7867

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Distributed by: Sam's West, Inc., Bentonville, AR 72716



**Compare to Nicorette® Gum active ingredient\***

NDC 68196-011-02



**Sugar Free Nicotine Gum**  
 Nicotine Polacrilex Gum USP (nicotine)  
 Stop Smoking Aid



**Member's Mark.**



**Original Flavor**

**Sugar Free Nicotine Gum**

Nicotine Polacrilex Gum USP (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

Blister packaged for your protection. Do not use if individual seals are open or torn.  
 • 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.



actual size  
 Original Flavor

**396 Pieces**

**100% MONEY BACK GUARANTEE**  
 QUALITY AND PERFORMANCE  
 We will gladly buy back any unused or unexpired Nicorette Nicotine Gum USP (nicotine) you call us at 1-877-440-7867 from 9:00 a.m. to 5:00 p.m. CT Monday - Friday.

**Nicotine Gum**

Nicotine Polacrilex Gum USP (nicotine)  
 Stop Smoking Aid



DP22756

**Nicotine Polacrilex Gum USP 4 mg Original Flavor**

**Principal Display Panel**

DP23483





Principal Display Panel

DP23483

**Apply These Stickers To Your Calendar** 

**Aplique estas calcomanías a su calendario**

**Step 1. • Paso 1.**



1 piece every 1 to 2 hours  
1 goma de mascar cada 1 a 2 horas

*At the Beginning of Week # 1. (Quit Date)*  
*Al comienzo de la semana n.°1*  
*(Fecha en la que dejará de fumar)*

**Step 2. • Paso 2.**



1 piece every 2 to 4 hours  
1 goma de mascar cada 2 a 4 horas

*At the Beginning of Week # 7.*  
*Al comienzo de la semana n.°7*

**Step 3. • Paso 3.**



1 piece every 4 to 8 hours  
1 goma de mascar cada 4 a 8 horas

*At the Beginning of Week # 10.*  
*Al comienzo de la semana n.°10*

**EX SMOKER**



**EX FUMADOR**

*12 Weeks After Quit Date*  
*12 semanas después de la fecha en la que dejará de fumar*

231566-01 R0518

**NICOTINE**

nicotine polacrilex gum, chewing

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-010
<b>Route of Administration</b>	ORAL		

**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)	
POLACRILIN (UNII: RCZ785HI7S)	
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 (biconvex)	Size	14mm
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-010-02	396 in 1 CARTON	10/16/2017	
1		33 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	10/16/2017	06/30/2021

## NICOTINE

nicotine polacrilex gum, chewing

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-011
Route of Administration	ORAL		

### 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)				
POLACRILIN (UNII: RCZ785HI7S)				
<b>Product Characteristics</b>				
Color	yellow	Score	no score	
Shape	SQUARE (biconvex)	Size	14mm	
Flavor		Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-011-02	396 in 1 CARTON	10/16/2017	
1		33 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	10/16/2017		

**Labeler** - Sam's West, Inc. (051957769)