

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

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**Nicotine Gum Ice Mint**

**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 8 mg
- **(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**

**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

DP22756

DP22757

**Principal Display Panel**

Compare to Nicorette<sup>®</sup> Gum  
White Ice Mint<sup>®</sup> active ingredient\*

NDC 68196-013-01

Member's Mark<sup>™</sup>

2 mg

COATED Ice Mint 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  
COATED Ice Mint Flavor

231  
Pieces

\*Nicorette® White Ice Mint® are registered trademarks of GlaxoSmithKline Consumer Healthcare, L.P.

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

DP22756

**Drug Facts**

**Active Ingredient** (in each chewing piece) Nicotine Polacrilex, 2 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**

- 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.

\*Nicorette® White Ice Mint® are registered trademarks of GlaxoSmithKline Consumer Healthcare, L.P. This product is not affiliated with GlaxoSmithKline Consumer Healthcare, L.P.

**Drug Facts (continued)**

**Directions**

- if you are under 18 years of age, ask a doctor before use
- before using this product, read the enclosed Users 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:

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 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**

- each piece contains: calcium 115 mg, sodium 6 mg, store at 20° - 25°C (68°-77°F) • protect from light

**Inactive ingredient** ascorbic acid, acesulfame potassium, carnauba wax, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide and xylitol.

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

**Compare to Nicorette® Gum White Ice Mint® active ingredient\***

NDC 68196-013-01

**Member's Mark**

**Sugar Free Nicotine Gum**

Nicotine Polacrilex Gum USP (nicotine)  
Stop Smoking Aid

**2 mg**

**COATED Ice Mint 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**  
COATED Ice Mint Flavor  
**231 Pieces**

**100% MONEY BACK GUARANTEE**

**QUALITY AND PERFORMANCE**

We stand by the quality of our products. If you are not completely satisfied with your purchase, please call 1-877-440-7867 from 9 a.m. to 5 p.m. CT, Mon-Fri. Only.

Nicotine Polacrilex Gum USP 2 mg Ice Mint Flavor

## Principal Display Panel

Compare to Nicorette® Gum  
White Ice Mint® active ingredient\*

NDC 68196-014-01

Member's Mark™

4 mg

COATED Ice Mint 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

COATED Ice Mint Flavor

231

Pieces

\*Nicorette® White Ice Mint® are registered trademarks of GlaxoSmithKline Consumer Healthcare, L.P.

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DP22757

**Drug Facts**

**Active Ingredient** Purpose  
(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 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)

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**Drug Facts** (continued)

**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 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 6 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**  
• each piece contains: calcium 120 mg, sodium 6 mg  
• store at 20° - 25°C (68° - 77°F) - protect from light

**Inactive ingredients** acacia, acacia gum, potassium carmelum wax, D-C-yellow #10 aluminum lake, flavone gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide and xylitol.

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

\*"Nicorette" "White Ice Mint" are registered trademarks of GlaxoSmithKline Consumer Healthcare, LP. This product is not affiliated with GlaxoSmithKline Consumer Healthcare, LP.



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



# Compare to Nicorette® Gum White Ice Mint® active ingredient\*



NDC 68156-014-01



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

**COATED Ice Mint 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  
**COATED Ice Mint Flavor**  
**231 Pieces**

**100% MONEY BACK GUARANTEE**  
QUALITY AND PERFORMANCE  
We would like to hear from you about any comments or suggestions. Write comments, US or Canada, please call us at 1-877-440-7867. Fax to: 201-462-3121. © 2011

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



DP22757

## Nicotine Polacrilex Gum USP 4 mg Ice Mint Flavor

**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

DP23483\_User Guide\_231566-01\_R0518\_page3

**NICOTINE COATED ICE MINT**

nicotine polacrilex gum, chewing

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-013
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)	
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G)	
<b>POLACRILIN</b> (UNII: RCZ785HI7S)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

**Product Characteristics**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68196-013-01	231 in 1 CARTON	10/16/2017	
1		33 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA204794	10/16/2017	06/30/2021

**NICOTINE COATED ICE MINT**

nicotine polacrilex gum, chewing

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-014
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)	
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G)	
<b>POLACRILIN</b> (UNII: RCZ785HI7S)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	SQUARE (biconvex)	<b>Size</b>	14mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-014-01	231 in 1 CARTON	10/16/2017	
1		33 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA204833	10/16/2017	

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

Revised: 7/2021

Sam's West, Inc.