

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

Nicotine Gum Fruit 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:

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.

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:

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

- **(2 mg) each piece contains:** calcium 115 mg, sodium 8 mg
- **(4 mg) each piece contains:** calcium 115 mg, sodium 8 mg
- store at 20° - 25°C (68°-77°F)
- protect from light

Inactive ingredients (2 mg)

acacia, acesulfame potassium, carnauba wax, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide and xylitol.

Inactive ingredients (4 mg)

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, 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

DP22758

DP22759

Principal Display Panel

Compare to Nicorette[®] Fruit Chill[™]

Coated Gum active ingredient*

NDC 68196-015-01

Member's Mark[™]

2 mg

Coated Fruit 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 Fruit Flavor

231
Pieces

*Nicorette® Fruit Chill™ are trademarks of GlaxoSmithKline Consumer Healthcare, L.P. This product is not affiliated with GlaxoSmithKline Consumer Healthcare, L.P.

DP22758

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 • 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.	

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**Compare to Nicorette® Fruit Chill™
Coated Gum active ingredient***

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

2 mg

Coated Fruit 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 Fruit Flavor

**231
Pieces**

100% MONEY BACK GUARANTEE
QUALITY AND PERFORMANCE
We stand behind our product and guarantee our nicotine replacement products. If you are not satisfied, we will refund your purchase price. See package for details.

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 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 8	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 115 mg, sodium 6 mg, store at 20° - 25°C (68°-77°F) • protect from light

Inactive ingredients acacia, acesulfame potassium, carnauba wax, FDSC blue #2 lake, FDSC red #40, FDSC yellow #5 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, saccharose, talc, titanium dioxide and xylitol.

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

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

2 mg

Nicotine Polacrilex Gum USP 2 mg Fruit Flavor

Principal Display Panel

Compare to Nicorette® Fruit Chill™

Coated Gum active ingredient*

NDC 68196-016-01

Member's Mark™

4 mg

Coated Fruit 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 Fruit Flavor

231

Pieces

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

DP22759

Drug Facts

Active Ingredient (in each chewing piece) Nicotine Polacrilex... 4 mg (nicotine) ...Stop smoking aid

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

- 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
- regular 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 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 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 dizziness, 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 0 mg
- store at 20° - 25°C (68°-77°F) • protect from light

Inactive ingredients saccharin, acesulfame potassium, carnauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide, and xylitol.

Questions or comments? Call 1-877-440-7887

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



Compare to Nicorette® Fruit Chill™ Coated Gum active ingredient*



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



Coated Fruit 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 Fruit Flavor

231 Pieces

Single packaged for your convenience. 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.

100% MONEY BACK GUARANTEE
QUALITY GUARANTEED OR YOUR MONEY BACK.
We warrant \$8.00 (plus tax) from you when any chewing gum or nicotine patch is returned in its original packaging. See our website at 1-877-440-7887 for details. © 2010 GlaxoSmithKline Consumer Healthcare, LP.

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



Nicotine Polacrilex Gum USP 4 mg Fruit Flavor

Principal Display Panel

DP23483

Principal Display Panel

DP23483



DP23483_User Guide_231566-01_R0518_page3

NICOTINE COATED FRUIT FLAVOR

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-015
Route of Administration	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
ACACIA (UNII: 5C5403N260)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)
SODIUM BICARBONATE (UNII: 8MDF5V39QO)
SODIUM CARBONATE (UNII: 45P3261C7T)
SUCRALOSE (UNII: 96K6UQ3ZD4)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
XYLITOL (UNII: VCQ006KQ1E)
POLACRILIN (UNII: RCZ785HI7S)

Product Characteristics

Color	brown (light brown)	Score	no score
Shape	SQUARE (biconvex)	Size	14mm
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-015-01	231 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	ANDA079044	10/16/2017	06/30/2021

NICOTINE COATED FRUIT FLAVOR

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-016
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
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)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	
POLACRILIN (UNII: RCZ785HI7S)	

Product Characteristics

Color	white (light tan)	Score	no score
Shape	SQUARE (biconvex)	Size	14mm
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-016-01	231 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	ANDA079038	10/16/2017	

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