NICOTINE POLACRILEX ORIGINAL FLAVOR- nicotine polacrilex gum, chewing NICOTINE POLACRILEX ORIGIANL FLAVOR- nicotine polacrilex gum, chewing Publix Supermarkets, Inc.

Nicotine Polacrilex Gum 2 mg and 4 mg Original Flavor - Publix

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 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

- 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.

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 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.

Principal display panel 2 mg

*Compare to the active ingredient in Nicorette® Gum

SUGAR FREE

nicotinegum

NICOTINE POLACRILEX GUM USP, 2 mg (nicotine)

STOP SMOKING AID

ORIGINAL FLAVOR

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, 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 da 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 PUBLIX SUPER MARKETS, INC.,

3300 PUBLIX CORPORATE PARKWAY,

LAKELAND, FL 33811, 1-888-267-3037

Package label 2 mg



nicotinegum

NICOTINE POLACRILEX GUM USP, 2 mg (nicotine)



NDC 56062-606-62

nicotinegum

NICOTINE POLACRILEX GUM USP, 2 mg (nicotine)

STOP SMOKING AID

ORIGINAL FLAVOR

- 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

2 mg 110 PIECES OF GUM 2 mg EACH

*Compare to the active ingredient in Nicorette® Gum

TO INCREASE YOUR SUCCESS IN QUITTING:

- You must be motivated to quit.
- Use Enough Chew at least 9 pieces of Nicotine Polacrilex Gum per day during the first six weeks.
- Use Long Enough Use Nicotine Polacrilex Gum for the full 12 weeks.
- Use with a Support Program as directed in the enclosed User's Guide.



To remove the gum, tear off single unit.





Push gum through foil.

PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

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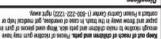
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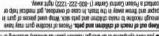
paper and throw away in the track, in case of overdose, gai medical help or confact a Poleon Control Center (1-500-222-1222) night away.

"This product is not menufactured or distributed by GlaxoSmithKine Consu-Healthcare, L.P., distributor of Miccorette® Cum.

Anactive ingredients accessions potassium, buylated hydronyloune, comarba wax, Tavors, gum base, sodium bioarbonate, sodium carbonate,

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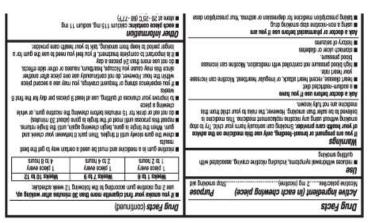


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sale cannot be verified source where proof of ■ Not for sale to those under 18 years of age.
■ Proof of age required.
■ Not for sale in vending







PUBLIX Nicotine Polacrilex Gum Original Flavor

Principal display panel 4 mg

*Compare to the active ingredient in Nicorette® Gum

SUGAR FREE

nicotine gum

NICOTINE POLACRILEX GUM USP, 4 mg (nicotine)

STOP SMOKING AID

ORIGINAL FLAVOR

FOR YHOSE WHO SMOKE THEIR FIRST CIGARETTE WITH 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

TO INCREASE YOUR SUCCES 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.

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3300 PUBLIX CORPORATE PARKWAY,

LAKELAND, FL 33811, 1-888-267-3037

Package label 4 mg



nicotinegum

NICOTINE POLACRILEX GUM USP, 4 mg (nicotine)



NDC 58062-809-82

SUGAR FREE

nicotinegum

NICOTINE POLACRILEX GUM USP, 4 mg (nicotine)

STOP SMOKING AID

ORIGINAL FLAVOR

- 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

110 PIECES OF GUM 4 mg EACH

*Compare to the active ingredient in Nicorette® Gum

TO INCREASE YOUR SUCCESS IN QUITTING:

- 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.
- Use Long Enough Use Nicotine Polacrilex Gum for the full 12 weeks.
- 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.

PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

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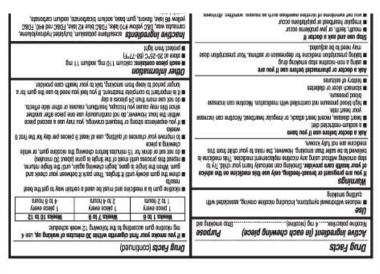
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- eu anober 18 years of age, ask a doctor before use

you have eymptoms of an allergic reaction (such as difficulty breathing or

"This product is not manufactured or d'etributed by GlasoSmithKline Con Healthsare, L.P., d'etributor of Nicoretta® Gum.









PUBLIX Nicotine Polacrilex GUM Original Flavor

NICOTINE POLACRILEX ORIGINAL FLAVOR

nicotine polacrilex gum, chewing

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:56062-608

Route of Administration BUCCAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of 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: 8MDF5V39Q0) 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:56062- 608-62	11 in 1 CARTON	01/01/2014	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
• • • • • • • • • • • • • • • • • • • •		Marketing Start Date	Marketing End Date
ANDA	ANDA074507	01/01/2014	

NICOTINE POLACRILEX ORIGIANL FLAVOR

nicotine polacrilex gum, chewing

Product Information				
	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-609
	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: 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			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:56062- 609-62	11 in 1 CARTON	01/01/2014		
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	01/01/2014	

Labeler - Publix Supermarkets, Inc. (006922009)

Revised: 12/2022 Publix Supermarkets, Inc.