

**NICOTINE POLACRILEX- nicotine polacrilex gum, chewing
QUALITY CHOICE (Chain Drug Marketing Association)**

**Nicotine Polacrilex Gum Coated Mint 2 mg ANDA078699 and 4 mg
ANDA078697 - Quality Choice**

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 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

- 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 8 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Other information - 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 or comments?

Call **1-877-440-7867**

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.



Instructions

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.**

Principal Display Panel - 2 mg

NDC 63868-168-20

QC

QUALITY CHOICE®

*Compare to the active ingredient in NICORETTE® Fresh Mint™

Sugar Free

Nicotine

Polacrilex

Gum USP,

2 mg (nicotine)

Stop Smoking Aid

Nicotine Polacrilex, 2 mg

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

2 mg

Coated

Mint Flavor

20 PIECES (2 MG EACH)

- TO INCREASE YOUR SUCCESS IN QUITTING:**
1. You must be motivated to quit.
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NDC 63868-168-20



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Sugar Free
Nicotine Polacrilex Gum USP, 2 mg (nicotine)

Stop Smoking Aid

Nicotine Polacrilex, 2 mg
FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

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2 mg

Coated Mint Flavor



20 actual size
PIECES (2 MG EACH)

232927 4/16



Drug Facts (continued)
Questions or comments?
Call 1-877-446-7667

Drug Facts (continued)
Inactive ingredients

Drug Facts (continued)
Other information

acacia, acesulfame potassium, carnauba wax, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, titanium dioxide and xylitol.

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

This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, LP, owner of the registered trademark "Nicorette®".
FREE AUDIO CD Upon Request. See Inside.

Distributed by Q.C.M.A., Inc.®
Natick, MA 01837-0985
www.qualitychoice.com
Questions: 248-449-9300

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Riskier packages for your protection. Do not use if individual seals are open or torn.



Push gum through foil.



Peel off backing starting at corner with tongue edge.



To remove the gum, tear off single unit.

Drug Facts

Active ingredient (in each chewing piece) Purpose
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 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

• 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.



X 2336334

Nicotine
Polacrilex
Gum USP,
4 mg (nicotine)

Stop Smoking Aid

Nicotine Polacrilex, 4 mg

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

4 mg

Coated
Mint Flavor

20 PIECES (4 MG EACH)

Drug Facts (continued)
Questions or comments?
Call 1-877-446-7667

Drug Facts (continued)
Inactive ingredients saccharin, 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.

Drug Facts (continued)
Other information
• each piece contains calcium 120 mg, sodium 8 mg
• store at 20 - 25°C (68 - 77°F)
• protect from light

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.

NDC 63868-167-20

QC QUALITY CHOICE

*Compare to the active ingredient in NICORETTE® Fresh Mint™

Sugar Free Nicotine Polacrilex Gum USP, 4 mg (nicotine)

Stop Smoking Aid

Nicotine Polacrilex, 4 mg
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

4 mg

Coated Mint Flavor

20 actual size
PIECES (4 MG EACH)

232928 4/16
6 35515 99535 2

Drug Facts (continued)
Active ingredient (in each chewing piece) Purpose
Nicotine polacrilex, 4 mg (nicotine) Stop smoking aid

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SAFETY ACTION
• 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.
• Recycle packages for your protection. Do not use if individual seals are open or torn.

FREE AUDIO CD Upon Request. See Inside.

Distributed by C.D.M.A., Inc.®
Noid, MD 48376-0985
www.qualitychoice.com
Questions: 248-449-9300

This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, LP, owner of the registered trademark "NICORETTE®".

Thrift surveillance-tag area

Push gum through foil.
Peel off backing starting at corner with loose edge.
To remove the gum, tear off single unit.

X 2336352

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-168
Route of Administration	BUCCAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg
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Inactive Ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color	white	Score	no score
Shape	SQUARE	Size	14mm
Flavor	MINT (coated mint)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-168-20	20 in 1 CARTON	07/01/2016	
1		1 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	ANDA078699	07/01/2016	07/01/2025

NICOTINE POLACRILEX
nicotitne polacrilex gum, chewing

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-167
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		
ACACIA (UNII: 5C5403N26O)				
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SODIUM CARBONATE (UNII: 45P3261C7T)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
XYLITOL (UNII: VCQ006KQ1E)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	SQUARE	Size	14mm	
Flavor	MINT (coated mint)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-167-20	20 in 1 CARTON	07/01/2016	
1		1 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	ANDA078697	07/01/2016	07/01/2025	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)