

**NICOTINE POLACRILEX- nicotine polacrilex gum, chewing
AAFES/Your Military Exchanges**

Nicotine Polarilex Gum Coated Mint 2 mg and 4 mg

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 (1-800-222-1222) 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.
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- 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal display panel 2 mg

Compare to the Active ingredient in Nicorette® Gum*

SUGAR FREE

NICOTINE POLACRILEX GUM USP, 2 MG (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

2mg

COATED MINT

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.
 - not for sale to those under 18 years of age
 - proof of age required
 - not for sale in vending machine 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:

PL Developments

200 Hicks Street

Westbury, NY 11590

Package display 2 mg

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To remove the gum, tear off single unit.



Peel off backing starting at corner with loose edge.



Push gum through foil.

Compare to the Active Ingredient of
Nicorette® Gum*

exchange **select™**

SUGAR FREE
**NICOTINE POLACRILEX
GUM USP, 2 MG (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 MINT

2 mg

100 PIECES

quality
value

exchange **select™**

2 mg

SUGAR FREE
**NICOTINE POLACRILEX
GUM USP, 2 MG (NICOTINE)**
STOP SMOKING AID

Manufactured by:
PL Developments
200 Hicks Street
Westbury, NY 11590

SATISFACTION GUARANTEED OR YOUR MONEY BACK.
Manufactured For Your Military Exchange

This product is not manufactured or distributed by GlaxoSmithKline Consumer
Healthcare, L.P., distributor of Nicorette® Gum.

Call 1-877-753-8838 Monday-Friday 9AM-5PM EST

Active Ingredients: Nicotine polacrilex, potassium carbonate, sodium
flavor, gum base, hydroxypropyl cellulose, magnesium oxide, sodium
carboxymethylcellulose, saccharin, methyl salicylate, xylitol

Questions or comments?

Step use and ask a doctor if:

- mouth, throat, or jaw problems occur
- tingling, numbness, or numbness 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)

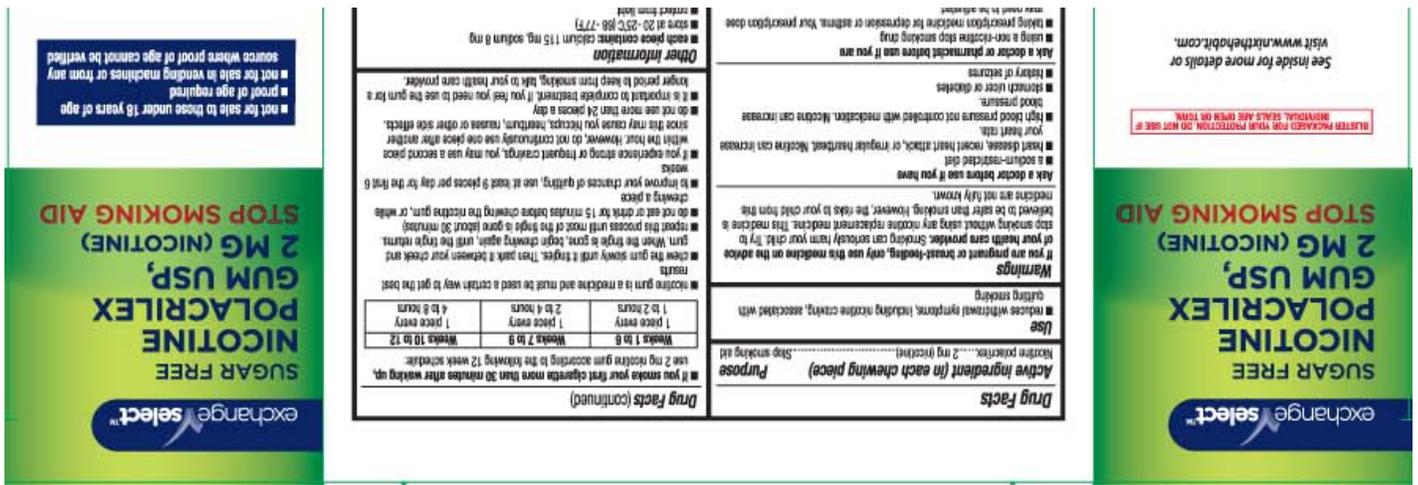
Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. When used, pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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



PLD-9817A F000592



EXCHANGE SELECT Nicotine Gum Mint Flavor

Principal display panel 4 mg

Compare to the Active Ingredient of Nicorette® Gum*

SUGAR FREE

NICOTINE POLACRILEX GUM USP, 4 MG (NICOTINE)

STOP SMOKING AID

FOR THOSE 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

COATED MINT

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BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE OPEN OR TORN

Manufactured For Your Military Exchange

Distributed by:

PL Developments

200 Hicks Street
Westbury, NY 11590

Package label 4 mg

TO INCREASE YOUR SUCCESS IN QUITTING:

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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.

Compare to the Active Ingredient of
Nicorette® Gum*

exchange **select**

SUGAR FREE
NICOTINE POLACRILEX GUM USP, 4 MG (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 MINT

4 mg

100 PIECES

quality value

exchange **select**

4 mg

SUGAR FREE
NICOTINE POLACRILEX GUM USP, 4 MG (NICOTINE)
STOP SMOKING AID



SATISFACTION GUARANTEED OR YOUR MONEY BACK.

Manufactured for your Money Back.™
PL Development
200 Main Street
Westbury, NY 11590

Other Alternatives
Nicotine Polacrilex Gum USP, 4 mg (Nicotine) Stop Smoking Aid is available in a variety of strengths and flavors. Your physician may recommend a different strength or flavor. For more information, call 1-877-739-8885 (Monday-Friday, 9AM-5PM EST).

Active Ingredients
Nicotine Polacrilex Gum USP, 4 mg (Nicotine) Stop Smoking Aid contains Nicotine Polacrilex, Nicotine, and other inactive ingredients.

Directions
Chew one piece of Nicotine Polacrilex Gum USP, 4 mg (Nicotine) Stop Smoking Aid slowly for 30 minutes after waking up. Do not swallow. If you are unable to chew, push the gum through the foil and place it in your mouth. Do not use if you are under 18 years of age, are pregnant, or have a heart condition. For more information, call 1-877-739-8885 (Monday-Friday, 9AM-5PM EST).

Warnings
Do not use if you are under 18 years of age, are pregnant, or have a heart condition. Do not use if you are under 18 years of age, are pregnant, or have a heart condition. For more information, call 1-877-739-8885 (Monday-Friday, 9AM-5PM EST).



See inside for more details or visit www.northhale.com

Not for sale in vending machines or from any source where proof of age cannot be verified.



EXCHANGE SELECT Sugar Free Nicotine Coated Mint

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-428
Route of Administration	BUCCAL		

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: 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:55301-428-44	100 in 1 CARTON	01/01/2014	
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	01/01/2014	

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-429
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: 9XZ 8H6N6OH)	
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:55301-429-44	100 in 1 CARTON	01/01/2014	
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	01/01/2014	

Labeler - AAFES/Your Military Exchanges (001695568)

Revised: 10/2023

AAFES/Your Military Exchanges