

NICOTINE POLACRILEX- nicotine polacrilex gum, chewing
AmerisourceBergen (Good Neighbor Pharmacy) 46122

Nicotine Polacrilex Gum Coated Ice Mint 4 mg ANDA204833 - Equate

Drug Facts

Active ingredient (in each chewing piece)

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

- **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

- **each piece contains:** calcium 120 mg, sodium 8 mg

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

Inactive ingredients

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

Compare to Nicorette® Gum active ingredient*

Nicotine Gum

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, 2 mg

Coated Mint Flavor

Sugar-Free

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivate 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

- 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:

AmerisourceBergen

1 West First Avenue,

Conshohocken, PA 19428

www.mygnp.com

Package Label

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.

NDC 46122-718-60

**GOOD
NEIGHBOR
PHARMACY®****Compare to
Nicorette® Gum
active ingredient*****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

Inactive ingredients

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, xylitol

Questions or comments?

Call 1-877-753-3935
Monday-Friday 9AM-5PM EST

*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:
AmerisourceBergen
1 West First Avenue,
Conshohocken, PA 19428
Questions or Concerns?
Visit us at www.mygnp.com



Product of Ireland

PLD-B623A
FC008301

Nicotine Gum

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

Sugar-Free

Coated
Mint Flavor

20 pieces,
4 mg each

actual
size

■ 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

Push gum
through foilPeel off backing
starting at corner
with loose edgeTo remove the
gum, tear off
single unit**Drug Facts****Active ingredient (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)

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

- 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.

ABC# 10271739



0 8770143477 8

GOOD NEIGHBOR PHARMACY Nicotine Gum Coated Mint Flavor**NICOTINE POLACRILEX**

nicotine polacrilex gum, chewing

Product Information**Product Type**

HUMAN OTC DRUG

Item Code (Source)

NDC:46122-718

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)				
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	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-718-60	20 in 1 CARTON	02/22/2023	
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	02/22/2023	

Labeler - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

Revised: 3/2023

AmerisourceBergen (Good Neighbor Pharmacy) 46122