

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

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**Drug Facts**

**Active ingredient (in each chewing piece)**

Nicotine polacrilex (equal to 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 your 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. If you need to remove the lozenge, wrap it 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. No studies have been done to show if this product will work for you.**
- 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 the process until most of the tingle is gone (about 30 minutes)
- do not eat or drink 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 11 mg
- store at 20-25°C (68-77°F)
- protect from light

## Inactive ingredients

acesulfame potassium, butylated hydroxytoluene, carnauba wax, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol, talc

## ***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, 2 mg (nicotine)

Stop Smoking Aid

Original Flavor

Sugar-Free

2 mg each

### **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

### **TO INCREASE YOUR SUCCESS IN QUITTING:**

- 1.** You must be motivated to quit.
- 2.** Use Enough - Use **at least 9** 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 Haleon group of companies, distributor of Nicorette® Gum

**See inside for more details or visit [www.nitthehabit.com](http://www.nitthehabit.com)**

**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 46122-719-60

**Compare to  
Nicorette® Gum  
active ingredient\***

**GOOD  
NEIGHBOR  
PHARMACY®**

**2 mg**

**Nicotine  
Gum**

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

Sugar-Free

Original Flavor

**20 pieces,  
2 mg each**

actual  
size

**not for sale to those under 18  
years of age**

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

Put gum through  
tongue.

Peel off backing  
starting at corner  
near loose edge.

To remove the gum,  
tear at single unit.

**Drug Facts (continued)**

**Other information**

- each piece contains:  
calcium 115 mg, sodium 11 mg
- store at 20-25°C (68 -77°F)
- protect from light

**Inactive ingredients**

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1 West First Avenue  
Conshohocken, PA 19428  
Questions or concerns?  
www.mygnp.com

**Product of Ireland**

ABC# 10292832 Rev 09/2024

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PLD-D619B FCO09226

**GOOD NEIGHBOR PHARMACY Nicotine Gum Original Flavor**

**Drug Facts**

| Active ingredient (in each chewing piece)         | Purpose          |
|---------------------------------------------------|------------------|
| Nicotine polacrilex (equal to 2 mg nicotine)..... | Stop smoking aid |

**Use** ■ reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

**Warnings**

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**Stop use and ask a doctor if**

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- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

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■ nicotine gum is a medicine and must be used a certain way to get the best results

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# NICOTINE

nicotine polacrilex gum, chewing

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:46122-719 |
| 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 |
|---------------------------------------------|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)     |          |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) |          |
| CARNAUBA WAX (UNII: R12CBM0EIZ)             |          |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO)       |          |
| SODIUM CARBONATE (UNII: 45P3261C7T)         |          |
| TALC (UNII: 7SEV7J4R1U)                     |          |

## Product Characteristics

|          |                       |              |          |
|----------|-----------------------|--------------|----------|
| Color    | white (off white/tan) | Score        | no score |
| Shape    | SQUARE                | Size         | 14mm     |
| Flavor   |                       | Imprint Code |          |
| Contains |                       |              |          |

## Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:46122-719-60 | 20 in 1 CARTON                                         | 09/30/2022           |                    |
| 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               | ANDA074507                               | 09/30/2022           |                    |

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

