

**NICOTINE POLACRILEX- nicotine polacrilex gum, chewing**  
**Rugby Laboratories, Inc.**

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**Nicotine Polacrilex Gum 2 mg and 4 mg Coated Cinnamon - Rugby**

***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:

<b>Weeks 1 to 6</b>	<b>Weeks 7 to 9</b>	<b>Weeks 10 to 12</b>
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:

<b>Weeks 1 to 6</b>	<b>Weeks 7 to 9</b>	<b>Weeks 10 to 12</b>
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 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

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

#### ***Inactive ingredients - 2 mg***

acacia, acesulfame potassium, butylated hydroxytoluene, carnauba wax, FD&C red #40, gum base, hydroxypropyl cellulose, hypromellose, natural and artificial cinnamon flavors, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide and xylitol.

### **Inactive ingredients - 4 mg**

acacia, acesulfame potassium, butylated hydroxytoluene, carnauba wax, FD&C red #40, gum base, hydroxypropyl cellulose, hypromellose, natural and artificial cinnamon flavors, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide and xylitol.

### **Questions or comments?**

Call 1-800-645-2158

### **Principal display panel 2 mg**

Compare to the active ingredient in Nicorette® Gum\*

### **Nicotine Gum**

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

### **Stop Smoking Aid**

2 mg

Coated Cinnamon Flavor Sugar-Free

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** - 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 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.

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

Distributed by:

RUGBY® LABORATORIES

Indianapolis, IN 46268

**Package label 2 mg**



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

BALSTEN 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.

<b>Drug Facts</b>	<p><b>Stop using and ask a doctor if:</b></p> <ul style="list-style-type: none"> <li>you are taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>you are taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are:</b></p> <ul style="list-style-type: none"> <li>pregnant, planning to get pregnant, or breastfeeding.</li> <li>taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> </ul>
<b>Warnings</b>	<p><b>Do not use if you are:</b></p> <ul style="list-style-type: none"> <li>pregnant, planning to get pregnant, or breastfeeding.</li> <li>taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> </ul>
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<b>Active ingredient (in each chewing piece)</b>	<p><b>Stop using and ask a doctor if:</b></p> <ul style="list-style-type: none"> <li>you are taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>you are taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>you are taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>you are taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> </ul>
<b>Drug Facts (continued)</b>	<p><b>Other information:</b></p> <ul style="list-style-type: none"> <li>Keep out of reach of children. Do not use if the seal is broken.</li> <li>Do not use if you are pregnant, planning to get pregnant, or breastfeeding.</li> <li>Do not use if you are taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>Do not use if you are taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>Do not use if you are taking a prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> <li>Do not use if you are taking a non-prescription drug for depression or anxiety, your prescription drug may need to be adjusted.</li> </ul>

**Rugby**

NDC 0538-3404-01

Compare to the active ingredient in Nicorette® Gum

**Nicotine Gum USP, 2 mg (Nicotine)**

**Stop Smoking Aid**

**Coated Cinnamon Flavor**

**2 mg**

**RUGBY Nicotine Gum Coated Cinnamon Flavor**

**Principal display panel 4 mg**

Compare to the active ingredient in Nicorette® Gum\*

**Nicotine Gum**

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

**Stop Smoking Aid**

4 mg

Coated Cinnamon Flavor

Sugar-Free

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

**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
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  - not for sale in vending machines or from any source where proof of sge csnot be verified

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

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

Distributed by:

**RUGBY® LABORATORIES**

Indianapolis, IN 46268

**Package label 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 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 edges.



Push gum through foil.



NDC 0536-3405-01

Compare to the active ingredient in Nicorette® Gum\*

# Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

## Stop Smoking Aid

**4 mg**

Coated Cinnamon Flavor  
Sugar-Free



Actual Size

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

**100 Pieces, 4 mg EACH**



# Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

Stop Smoking Aid **4 mg**



RW 0124 R 50 Re-order No. 37023

FD-0828B F008868  
Gum USP, 2 mg  
waking up, use Nicotine Polacrilex

If you smoke your first cigarette **MORE THAN 30 MINUTES** after WAKING UP

**Sugar-Free**

Exp. Date: \_\_\_\_\_  
Lot No.: \_\_\_\_\_

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Contains: nicotine, natural and artificial cinnamon flavors, sodium benzoate, sodium carbonate, sucrose, talc, titanium dioxide, xylitol

**Directions**  
If you are under 18 years of age, use a doctor before use  
Before using this product, read the enclosed User's Guide for complete directions and other important information  
Do not use the gum for your gum day  
If you smoke your first cigarette more than 30 minutes after waking up, use 2 mg Nicotine Gum

**Warnings**  
If you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat  
If 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 residue to make children and pets sick. When used piece 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.

**Questions or comments?**  
Call 1-877-753-3869 Monday-Friday 9AM-5PM CST

Distributed by:  
**RUGBY LABORATORIES**  
Indianapolis, IN 46268  
(800) 616-2471  
www.rugbypharmaceuticals.com

\*This product is not manufactured or distributed by the parent group of companies.  
Distributor of Nicorette® Gum.



<b>Color</b>	pink (light pink)	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>	CINNAMON	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-3404-37	40 in 1 CARTON	07/08/2009	08/31/2014
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-3404-01	100 in 1 CARTON	07/08/2009	
2		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	ANDA079216	07/08/2009	

## NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-3405
<b>Route of Administration</b>	BUCCAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	

<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

### Product Characteristics

<b>Color</b>	pink (dark pink)	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>	CINNAMON	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-3405-37	40 in 1 CARTON	07/08/2009	07/31/2015
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-3405-01	100 in 1 CARTON	07/08/2009	
2		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	ANDA079219	07/08/2009	

**Labeler** - Rugby Laboratories, Inc. (079246066)

Revised: 3/2024

Rugby Laboratories, Inc.