

**RUGBY NICOTINE POLACRILEX GUM, COATED MINT FLAVOR- nicotine  
polacrilex gum, chewing  
Rugby Laboratories, Inc.**

-----  
**Nicotine Polacrilex Gum 2 mg and 4 mg Coated Mint - 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 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, 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, 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\*

**Nicotine Gum**

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

**Stop Smoking Aid**

2 mg

Coated Mint 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 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.

**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**

**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 edge.



Push gum through  
foil.



NDC 0538-3112-01

Compare to the active ingredient  
in Nicorette® Gum\*

# Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg  
(Nicotine)

**Stop Smoking Aid**

**2 mg**

**Coated Mint Flavor  
Sugar-Free**



Actual Size

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

**100 Pieces, 2 mg EACH**



# Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg  
(Nicotine)

**Stop Smoking Aid 2 mg**



Rev. 01/24 N-58 No. order No. 370056  
FDJ-06178 F0009661

**FOR THOSE WHO SMOKE  
WITHIN 30 MINUTES  
AFTER WAKING UP**  
If you smoke your first cigarette  
up, use Nicotine Polacrilex Gum  
USP, 4 mg

**Sugar-Free**

**Active ingredients:** acetic acid, acetylcholine, nicotine, sodium  
tartrate, gum base, hydroxypropyl cellulose, neohesperidin, sodium  
benzoate, sodium carboxymethyl cellulose, xanthan gum, glycerin

**Questions or comments?**  
Call 1-877-755-3005 Monday-Friday 9AM-5PM EST

\*This product is not manufactured or distributed by the same group of companies.

Distributed by:

**RUGBY LABORATORIES**

Indianapolis, IN 46268

(800) 616-2471

www.majopharmaceuticals.com

**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  
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.  
If you have symptoms of an allergic reaction (such as difficulty breathing or rash)  
diarrhea, weakness, and rapid heartbeat  
If you get symptoms of nicotine overdose such as nausea, vomiting, diarrhea,  
regular heartbeat or palpitations occur  
If you have heart, or jaw problems occur

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

Distributed by:

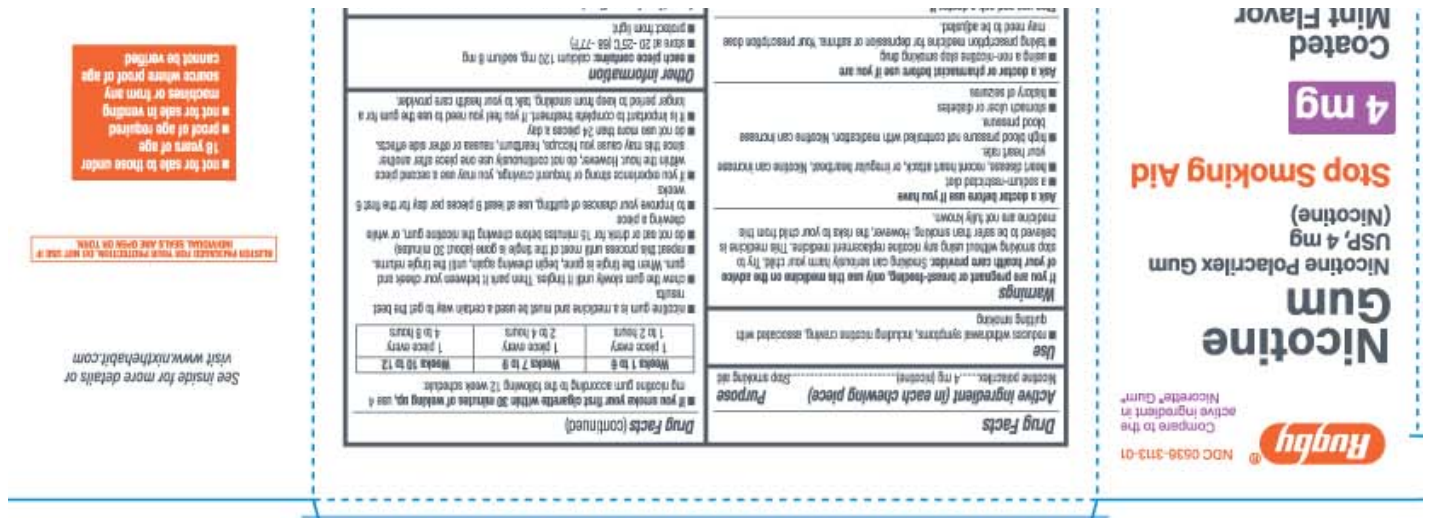
**RUGBY® LABORATORIES**

Indianapolis, IN 46268

**Package label 4 mg**







RUGBY Nicotine Gum Coated Mint Flavor

## RUGBY NICOTINE POLACRILEX GUM, COATED MINT FLAVOR

nicotine polacrilex gum, chewing

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-3112
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: 3A3U0G171G)	
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:0536-3112-01	10 in 1 CARTON	12/29/2008	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-3112-37	4 in 1 CARTON	12/29/2008	
2		10 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	12/29/2008	

## RUGBY NICOTINE POLACRILEX GUM, COATED MINT FLAVOR

nicotine polacrilex gum, chewing

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-3113
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)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
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

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>	MINT (coated mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-3113-37	4 in 1 CARTON	12/29/2008	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-3113-01	10 in 1 CARTON	12/29/2008	
2		10 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	12/29/2008	

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

Revised: 3/2024

Rugby Laboratories, Inc.