# 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:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every	1 piece every	1 piece every
1 to 2 hours	2 to 4 hours	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 piece every	1 piece every
1 to 2 hours	2 to 4 hours	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 CIGARETTEMORE THAN 30 MINUTES AFTER WAKING UP

If you smoke your first cigarette <u>WITHIN</u> 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

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

Distributed by:

#### **RUGBY® LABORATORIES**

Indianapolis, IN 46268

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

### 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.



tear off single unit.





Peel off backing starting at corr with loose edge



## **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

अक्रक चंद्र

1742-818 (008) Basah VI ,aloqunahni Distributed by: RUGBY\* LABORATORIES

"The product is not manufactured or distributed by Halloon group of componen. destributor of Moovette" Gurn.

CPL 1-813-3832 Wordsy-Frances SPM-SPM EST

wectow with working score science is observed on the processor country of posterior solds of the processor o

We obscure the Wester of age, sake decord betwee see at the own washer 16 years of a decord between the cuspiests and the contract and the straybase in the construction of characters and other straybase in the construction of characters and other straybase in the construction of decords and the construction of the construction of the construction of the construction of the con-traction of the construction of the cons und auccourful a

Neep out of reach of children and pelbs. Please of ricicioles gunt may have enough receive a color handle out of the children and pelbs and be seen out of the pelbs and pelbs and be seen out of the pelbs and pelbs an

m mouth, leith, or jow problems occu: m mogeth insultable of shockers occu: prougle springers of knobles occus occusion, comiting, ducineral, dearhea, weakness, and more it seedon leach as difficulty breathing or marin m you here springers of an always reaction leach as difficulty breathing or marin

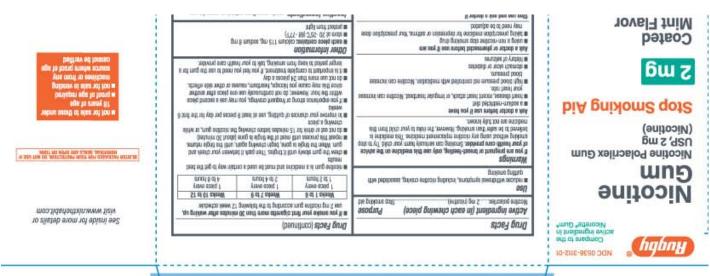


198800034 BZ190-07M

Bm + 'ASU up, use Nicotine Polacrilex Gum WITHIN 30 MINUTES of waking If you smoke your first cigarette

> ALTER WAKING UP THEIR FIRST CIGARETTE FOR THOSE WHO SMOKE

> > Sugar-Free



**RUGBY Nicotine Gum Coated Mint 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 Mint Flavor

Sugar-Free

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP

If you smoke your first cigarette <u>MORE THAN</u> 30 MINUTES after waking up, use Nicotine Polacrilex Gum USP, 2 mg

### TO INCREASE YOUR SUCCESS UN 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

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

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

Distributed by:

**RUGBY® LABORATORIES** 

Indianapolis, IN 46268

Package label 4 mg

#### TO INCREASE YOUR SUCCESS IN QUITTING:

- You must be motivated to quit.
- Use Enough Chew at least 9 pieces of Nicotine Polacrilex Gum per day during the first six weeks.
   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.



tear off single unit.



Peel off backing starting at come





#### NDC 0538-3113-01

Compare to the active ingredient in Nicorette\* Gum\*

### **Nicotine Gum**

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

### Stop Smoking Aid

### Coated Mint 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

ENT DRIN

TON SET

www.majorphiermaceubcaia.com Distributed by: BUGBY\* LABORATORIES Indianapolis, IN 46268 TASS-363 (008)

This product is not manufactured or distributed by Haleon group of companies, distributor of Wiccrebs<sup>®</sup> Gun.

Questions or comments?

260, sew inturmor, nutreatio; emitiereo autore **Stroilbengnii evitoreni** geschilto hypropeolegi, asad mup<sub>a</sub>mora, jusa inturiasi bir videy godoli musikii jale, man indos, laskindra mubos, jale inturiasi bir selekti. Ediya

Directions:

If you are make 18 years at age, sak a decider State are complete and year are make 18 years at a decider inspector arbitrariation and being the product interests and being the product interests and year large way to a permitted and if you are look year first complete up.

Les 2 men mestine gurn.

Neep and of reach of children and polic, Pieces of richticing pure of children and polic, Pieces of richticing pure of the center of the children and policy of pieces of vertices, galf medical help or contact, a Policen Control Control Control Control Control Control Control Control

m ivon twee symptoms of an allergic machon (such as difficulty breathing or TENCHESI DIQEI DRS (SENTREW LEGITIED and the sense are a sense of a se



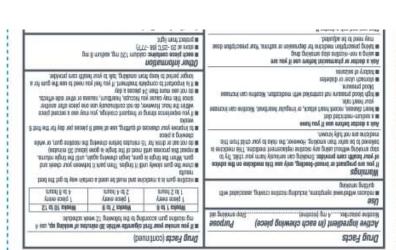
Gum USP, 2 mg waking up, use Nicotine Polacniex MORE THAN 30 MINUTES after If you smoke your first cigarette

> THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF FOR THOSE WHO SMOKE

> > Sugar-Free



see inside for more details or





#### **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

NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)

NICOTINE 2 mg

Ingredient Name

Strength

ACACIA (UNII: 5C5403N26O)

ACESULFAME POTASSIUM (UNII: 230V73Q5G9)

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				

P	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 Application Number or Monograph Marketing Start Marketing End Category Citation Date 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
<b>ACACIA</b> (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
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				
Color	yellow	Score	no score	
Shape	SQUARE	Size	14mm	
Flavor	MINT (coated mint)	Imprint Code		
Contains				

P	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 Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
ANDA	ANDA078697	12/29/2008		

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

Revised: 3/2024 Rugby Laboratories, Inc.