

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

Nicotine Polacrilex Gum 2 mg and 4 mg 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 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:

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 our 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

carnauba wax, flavors, gum base, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, xylitol.

Inactive ingredients - 4 mg

carnauba wax, flavors, gum base, magnesium oxide, sodium bicarbonate, sodium carbonate, talc, 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 m (Nicotine)

Stop Smoking Aid

2 mg

Uncoated 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 Haleon group of companies, distributor of Nicorette® Gum.

BLISTER 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 0536-1362-23

Compare to the active ingredient in Nicorette® Gum*

Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

Stop Smoking Aid

2 mg

Uncoated 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

110 Pieces, 2 mg EACH



Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

Stop Smoking Aid 2 mg



PL-08188 F008971
Rev. 01/16 R-58 Re-order No. 370095

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 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

Directions
If you are under 18 years of age, ask a doctor before use.
If you are using the product, read the enclosed User's Guide for complete directions and other important information.
As soon as you 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. Keep 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.

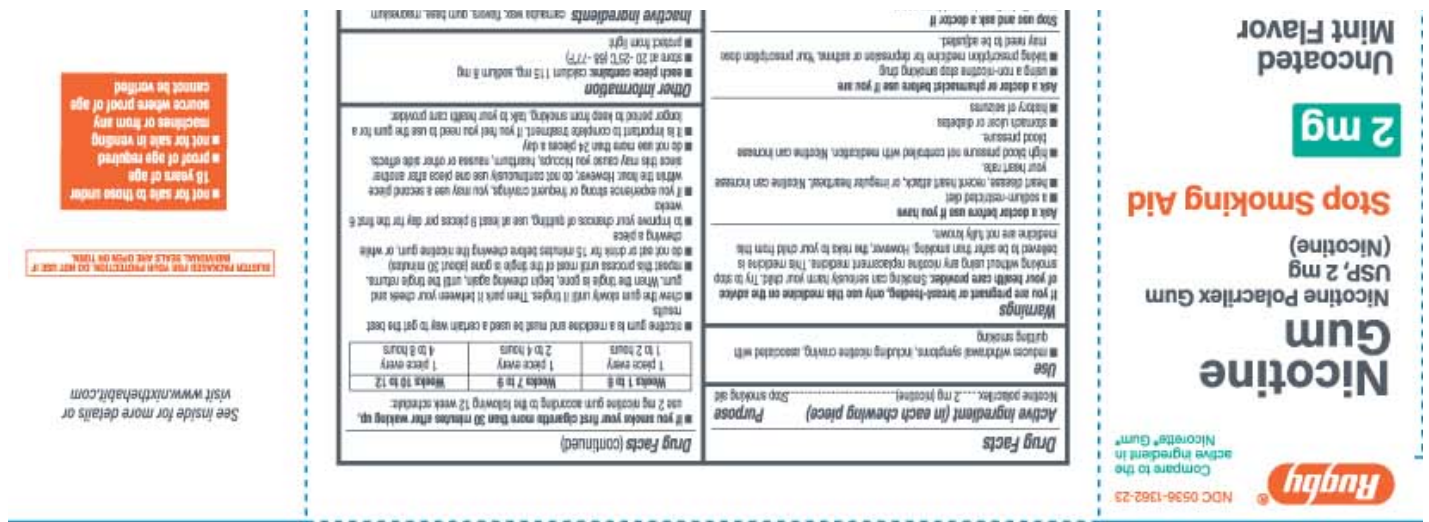
Warnings
Do not use if you have symptoms of an allergic reaction (such as difficulty breathing or rash), asthma, weakness, and rapid heartbeat.
Do not get pregnant or become pregnant while using this product.

Other information
This product is not for use in children.
Keep out of reach of children and pets.
Keep out of reach of children and pets.

Distributed by:
RUGBY LABORATORIES
Indianapolis, IN 46288
(800) 616-2471
www.majorpharmaceuticals.com

Questions or comments?
Call 1-877-752-3838 Monday-Friday, 9AM-5PM EST.
The product is not manufactured or distributed by Hekkon group of companies.
Distributor of Nicorette® gum.
©2016 Rugby Laboratories, a subsidiary of Hekkon group of companies.

Exp. Date:
Lot No.:



RUGBY Nicotine Gum Uncoated 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

Uncoated Mint 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
 - 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.

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

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 0536-1372-23

Compare to the active ingredient in Nicorette® Gum*

Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

Stop Smoking Aid

4 mg

Uncoated 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

110 Pieces, 4 mg EACH



Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (Nicotine)

Stop Smoking Aid **4 mg**

Exp. Date:

Lot No.:

Directions

If you are under 18 years of age, ask a doctor before use.
 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 after waking up, use 4 mg nicotine gum.
 If you are using the product, read the enclosed User's Guide for complete directions and other important information.
 If you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, dizziness, weakness, and rapid heartbeat, stop chewing and seek medical help or contact a Poison Control Center (1-800-222-1222) right away.
 Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. When 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), stop use immediately.

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. When 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.

Questions or comments?
 Call 1-877-762-8226 Monday-Friday 9AM-5PM EST.
 ©2005, 2006 Nicorette, Inc. All rights reserved. Nicorette, Nicotine Gum, and Nicotine Polacrilex are trademarks of Nicorette, Inc.

Distributed by:
RUGBY LABORATORIES
 Indianapolis, IN 46256
 (800) 616-2471
 www.majopharmaceuticals.com



Sugar-Free

FOR THOSE WHO SMOKE THEIR **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

Nicotine Polacrilex Gum USP, 4 mg

Uncoated
Mint Flavor

4 mg

Stop Smoking Aid

(Nicotine)
USP, 4 mg
Nicotine Polacrilex Gum

Nicotine
Gum

Compare to the
active ingredient in
Nicorette® Gum*
NDC 0536-1372-25



Drug Facts (continued)	Warnings	Use								
<p>Drug Facts (continued)</p> <p>If you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine gum according to the following 12 week schedule:</p> <table border="1"> <tr> <td>Weeks 1 to 6</td> <td>1 piece every 2 to 4 hours</td> <td>Weeks 7 to 8</td> <td>1 piece every 4 to 8 hours</td> </tr> <tr> <td>Weeks 9 to 12</td> <td>1 piece every 4 to 8 hours</td> <td>1 piece every 4 to 8 hours</td> <td>1 piece every 4 to 8 hours</td> </tr> </table> <p>Other Information</p> <p>Each piece contains sodium 120 mg, sodium 8 mg (from gum base).</p> <p>Other Information</p> <p>Keep gum in original container. Do not use if the gum has a strong, unpleasant odor or taste. Do not use if the gum is broken, crumbly, or otherwise damaged.</p>	Weeks 1 to 6	1 piece every 2 to 4 hours	Weeks 7 to 8	1 piece every 4 to 8 hours	Weeks 9 to 12	1 piece every 4 to 8 hours	1 piece every 4 to 8 hours	1 piece every 4 to 8 hours	<p>Warnings</p> <p>If you are pregnant or breast-feeding, only use the 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 intended to help you quit smoking. However, the risks to your child from this medicine are not fully known.</p> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. high blood pressure not controlled with medicine. Nicotine can increase blood pressure. stomach ulcer or diabetes. history of seizure. <p>Ask a doctor or pharmacist before use if you are:</p> <ul style="list-style-type: none"> using a non-nicotine stop smoking drug. using prescription medicine for depression or anxiety. Your prescription dose may need to be adjusted. <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> you need to be advised. 	<p>Use</p> <p>Do not use with other nicotine replacement products, including nicotine chewing gum, associated with addiction smoking.</p> <p>Purpose</p> <p>Active ingredient (in each chewing piece): Nicotine polacrilex, 4 mg (nicotine). Stop smoking aid.</p>
Weeks 1 to 6	1 piece every 2 to 4 hours	Weeks 7 to 8	1 piece every 4 to 8 hours							
Weeks 9 to 12	1 piece every 4 to 8 hours	1 piece every 4 to 8 hours	1 piece every 4 to 8 hours							

is not for sale to those under 18 years of age
a proof of age required
is not for sale in vending machines or from any source where proof of age cannot be verified

AFTER PURCHASED FROM YOUR PHARMACY, DO NOT USE IT

See inside for more details or visit www.nicthehabit.com

RUGBY Nicotine Gum Uncoated Mint Flavor

RUGBY NICOTINE POLACRILEX GUM, MINT FLAVOR

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1362
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MAGNESIUM OXIDE (UNII: 3A3U0G171G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white (off-white to tan)	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:0536-1362-34	2 in 1 CARTON	07/29/2004	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-1362-06	5 in 1 CARTON	07/29/2004	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0536-1362-23	11 in 1 CARTON	07/29/2004	
3		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	ANDA076569	07/29/2004	

RUGBY NICOTINE POLACRILEX GUM, MINT FLAVOR

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1372
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white (off-white to tan)	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:0536-1372-34	2 in 1 CARTON	07/29/2004	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-1372-06	5 in 1 CARTON	07/29/2004	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0536-1372-23	11 in 1 CARTON	07/29/2004	
3		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	ANDA076568	07/29/2004	

Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 3/2024

Rugby Laboratories, Inc.