

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

Nicotine Polacrilex Gum 2 mg and 4 mg Original Flavor - 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 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 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

Other information - 4 mg

- **each piece contains:** calcium 110 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients - 2 mg

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

Inactive ingredients - 4 mg

acesulfame potassium, butylated hydroxytoluene, carnauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, 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 2 mg

Compare to the active ingredient in Nicorette® Gum*

Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

Stop Smoking Aid

2 mg Uncoated Original 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

Drug Facts

Active ingredient (in each chewing piece) **Purpose**
Nicotine polacrilex.....2 mg (nicotine) 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
■ 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)

Drug Facts (continued)

■ 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
■ 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

*This product is not manufactured or distributed by Haleon group of companies, distributor of Nicorette® Gum.

NDC 0536-3029-06

Compare to the active ingredient in Nicorette® Gum*

Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (Nicotine)

Stop Smoking Aid

2 mg

Uncoated Original 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

50 Pieces, 2 mg EACH

■ 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 PROTECTIVE SEAL IS BROKEN OR IF GUM PIECES ARE OFFER OR TORN.

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.

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

PLD-06198 F0008976
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Lot No.:
Exp. Date:

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

RUGBY Nicotine Gum Uncoated Original 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 Original 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

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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

Strength

ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SODIUM CARBONATE (UNII: 45P3261C7T)				
SORBITOL (UNII: 506T60A25R)				
TALC (UNII: 7SEV7J4R1U)				
Product Characteristics				
Color	white (off-white to 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:0536-3029-23	11 in 1 CARTON	03/15/1999	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-3029-34	2 in 1 CARTON	03/15/1999	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0536-3029-06	5 in 1 CARTON	03/15/1999	
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		ANDA074507	03/15/1999	

RUGBY NICOTINE POLACRILEX GUM, ORIGINAL FLAVOR			
nicotine polacrilex gum, chewing			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-3030
Route of Administration	BUCCAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg
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Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	yellow (yellowish)	Score	no score
Shape	SQUARE	Size	14mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-3030-23	11 in 1 CARTON	03/19/1999	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-3030-06	5 in 1 CARTON	03/19/1999	
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	ANDA074707	03/19/1999	

Labeler - Rugby Laboratories, Inc. (079246066)