

NICOTINE POLACRILEX- nicotine polacrilex gum, chewing
Rugby Laboratories

Nicotine Polacrilex Gum 2 mg and 4 mg Coated Cinnamon

Drug Facts

Active ingredient (in each chewing piece) - 2 mg

Nicotine polacrilex (equal to 2 mg nicotine)

Active ingredient (in each chewing piece) - 4 mg

Nicotine polacrilex (equal to 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 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 115 mg, sodium 11 mg
- 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 lake, 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 lake, gum base, hydroxypropyl cellulose, hypromellose, natural and artificial cinnamon flavors, sodium bicarbonate, sodium carbonate, sucralose, 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 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 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

(800) 616-2471

www.major-rugby.com

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 0536-3404-01

compare to the active ingredient in Nicorette® Gum*

nicotine gum

nicotine polacrilex gum USP, 2 mg (nicotine)
stop smoking aid

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

sugar free
coated
cinnamon
flavor

2 mg

100 pieces, 2 mg each



NDC 0536-3404-01

nicotine gum

nicotine polacrilex gum USP, 2 mg (nicotine)



Rugby 02/76 R-68 Re-order No. 30118

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

Stop use and seek a doctor if

- regular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, dizziness, weakness, and rapid heartbeat
- oral bleeding occurs
- 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 melt enough to make children and pets sick. They used pieces of gum in case and threw away in the trash. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) night 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
- Chew using the gum on your gum day
- If you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine gum

Inactive ingredients include: croscarmellose potassium, butylated hydroxytoluene, carboxymethyl cellulose, gum base, polyethylene glycol, polyethylene glycol, natural and artificial cinnamon flavors, sodium citrate, hypromellose, natural and artificial cinnamon flavors, sodium croscarmellose, sodium croscarmellose, sucralose, sac, titanium dioxide, yellow 6.

Questions or comments?
Call 1-877-753-9355 Monday-Friday 9AM-5PM EST

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

Distributed by:
RUGBY LABORATORIES
Indianapolis, IN 46258
(800) 616-2471
www.major-rugby.com
Product of United Kingdom

Distributed by:

RUGBY® LABORATORIES

Indianapolis, IN 46268

(800) 616-2471

www.major-rugby.com

Package label 4 mg

FD-0820C F0098771

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

ALTOFFER FINANCIAL DEALS ARE OPEN ON TUESDAY

Drug Facts

Warnings

Use

Warnings

Other information

Inactive ingredients

Drug Facts (continued)



RUGBY Sugar Free Nicotine Polacrilex Coated Cinnamon Flavor

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-3404
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: 5C5403N260)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3W0)	
SODIUM BICARBONATE (UNII: 8MDF5V39Q0)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	pink (light pink)	Score	no score
Shape	SQUARE	Size	14mm

Flavor	CINNAMON	Imprint Code	
Contains			

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-3405
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)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color	pink (dark pink)	Score	no score
Shape	SQUARE	Size	14mm
Flavor	CINNAMON	Imprint Code	
Contains			

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 (079246066)