

**RUGBY NICOTINE POLACRILEX GUM, ORIGINAL FLAVOR- nicotine polacrilex gum,
chewing
ATLANTIC BIOLOGICALS CORP.**

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 and 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 and talc.

DISTRIBUTED BY:

ALTANTIC BIOLOGICALS CORP.

20101 N.E 16 th PLACE

MIAMI, FL 33179

Questions or comments?

Call 1-877-440-7867

TO INCREASE YOUR SUCCESS IN QUITTING:



To remove the gum, tear off single unit.



Peel off backing starting at corner with loose edge.



Push gum through foil.

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.

PRINCIPAL DISPLAY PANEL - 2 mg

ATLANTIC BIOLOGICALS CORP.

NDC 17856-3030-1

COMPARE TO THE ACTIVE INGREDIENTS OF NICORETTE® GUM*

SUGAR FREE

NICOTINE Polacrilex GUM

USP, 4 mg (nicotine)

4 mg ORIGINAL

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, 2 mg

50 chewing pieces

NDC 17856-3030-01
Nicotine Polacrilex
Gum

4 mg (nicotine)

Mint Flavor / Sugar Free

COMPARE TO the active ingredient of NICORETTE® GUM

PACKAGING INFORMATION:

1 piece per Unit Dose Pouch

Piece(s) per Case: 50

See Package Insert for Drug Information.

Other Information:

Store at 20°- 25°C (68°- 77°F) Protect from light

Each piece contains: calcium 110 mg and sodium 11 mg

**KEEP NICOTINE POLACRILEX GUM AND ALL MEDICINES
OUT OF REACH OF CHILDREN**

Repackaged by: Unit Dose Solutions, Inc., Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.

20101 N.E. 16th Place

Miami, FL 33179

*Retain box label and package insert for drug information.

Questions or Comments:

Call 1-800-509-7592

UDS-Lot No: XXXXXX

MFG Lot No: XXXXXXXX

Exp Date: XX/XX/XXXX



17856303001

RUGBY NICOTINE POLACRILEX GUM, ORIGINAL FLAVOR

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-3030(NDC:0536-3030)
Route of Administration	BUCCAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
Does not contain	SUCROSE (UNII: C151H8M554)	0

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:17856-3030-1	50 in 1 CASE	06/05/2018	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074707	06/05/2018	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-3030) , relabel(17856-3030)

